Promoting effective reproductive health care

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Abstract

This thesis is concerned with approaches used by the Scottish Programme for Clinical Effectiveness in Reproductive Health (SPCERH) to improve quality of care. The work embraces two main themes: understanding factors that influence clinical practice; and evaluating strategies to improve practice.

Many factors influence practice, such as the nature of targeted behaviours, professionals and organisations (Chapter 1). An observational study, of practice related to 42 audit recommendations in 16 gynaecology units, found that attributes of recommendations independently modified the effects of a national audit and feedback project (Chapter 2). Four evaluations of dissemination and implementation strategies were conducted. The first, a telephone survey of 201 obstetricians and midwives, highlighted gaps in awareness of national recommendations on the prevention of maternal mortality (Chapter 3). The second, a before-and-after postal survey of 92 obstetricians, found mixed changes in self-reported practice following the dissemination of four national obstetric guidelines (Chapter 4). The third, an interrupted time series analysis, evaluated trends in the care of 1263 women in four maternity units related to of these guidelines, on mild, non-proteinuric hypertension in pregnancy (Chapter 5). No improvements in the appropriateness of initial investigations and subsequent clinical management were found. The fourth study, a cluster randomised trial involving all 26 gynaecology units in Scotland, evaluated a strategy to promote a guideline on induced abortion care. The strategy, delivered under the auspices of SPCERH, comprised audit and feedback, educational meetings, dissemination of a structured case record, and promotion of patient information. The strategy was refined in the light of barriers identified following a pre-intervention case record review, interviews with gynaecologists and a theoretically-derived survey of 151 clinical staff (Chapter 6). Post-intervention compliance with guideline recommendations was assessed by a review of 1474 case records and a survey of 1028 patients. No intervention effect was observed, possibly related to high pre-intervention compliance with selected recommendations and the appropriateness of the implementation strategy (Chapter 7).

The choices of study design were determined by SPCERHs' objectives, available time and resources. More rigorous designs were judged to be less susceptible to bias (Chapter 8). All studies were of moderate to high generalisability to secondary care professionals targeted by SPCERH activities. Recommendations are made for future evaluations of implementation activities (Chapter 9).

Declaration

I was responsible for all aspects of the design, conduct, analysis and writing up of the work in this thesis. The work was conducted with research collaborators from the Scottish Programme for Clinical Effectiveness in Reproductive Health (University of Edinburgh) and the Health Services Research Unit (University of Aberdeen). Individual contributions are detailed overleaf.

This work has not been submitted for any other degree or professional qualification.

Robbie Foy

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Contents

List of tables

List of figures

Glossary

Adjustment. A summarizing procedure for a statistical measure in which the effects of differences in composition of the populations being compared have been minimized by statistical methods

After study. A study in which observations are only made following an intervention, sometimes in more than one group of participants.

Association. Statistical dependence between two or more events, characteristics, or other variables. An association may be fortuitous or may be produced by various other circumstances; the presence of an association does not necessarily imply a causal relationship

Audit and feedback. Any summary of clinical performance of health care over a specified period of time. The summary may also include recommendations for clinical action. The information may be given in a written, electronic or verbal format.

Bias. Systematic deviation of results or inferences from the truth, or processes leading to such deviation.

Blind(ed) study. A study in which observer(s) and/or subjects are kept ignorant of the group to which the subjects are assigned.

Case study. A description of the process of change in a single group (e.g. of health care workers within a clinical team of unit).

Causality. The relating of causes to the effects they produce.

Clinical practice guideline. A systematically developed statement designed to assist practitioner and patient make decisions about appropriate health care for specific clinical circumstances.

Clinical governance. A system through which UK National Health Service (NHS) organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care.

Co-interventions. Interventions other than the treatment under study that are applied differently to the treatment and control groups.

Concealment of allocation. The process used to prevent foreknowledge of group assignment in a randomised controlled trial. The allocation process should be impervious to any influence by the individual making the allocation by having the randomisation process administered by someone who is not responsible for recruiting participants.

Confidence interval (CI). The range of numerical values in which we can be confident (to a computed probability, such as 90 or 95%) that the population value being estimated will be found.

Confounding variable (confounder). A variable that can cause or prevent the outcome of interest, is not an intermediate variable, and is associated with the factor under investigation. A confounding variable may be due chance or bias.

Construct validity. The validity of inferences about the higher order constructs that represent sampling variables.

Contamination. In randomised trials, the inadvertent application of the intervention being evaluated to the control group.

Controlled before-and-after (CBA) study. Data are collected in non-randomised study and control groups before and after the intervention is applied to study group. Differences in performance between the study and control groups following the intervention are assumed to be due to the intervention.

Cost-effectiveness analysis. An economic analysis that converts effects into health terms and describes the costs for some additional health gain.

Cross-sectional study. The observation of a defined population at a single point in time or time interval. Exposure and outcome are determined simultaneously.

Didactic educational meetings. Lectures or seminars without an interactive component.

Dissemination. Propagation of a message, e.g. by distribution of a clinical guideline.

Educational materials. Published or printed recommendations for clinical care, including clinical practice guidelines, audio-visual materials and electronic publications

Educational outreach visits. Use of a trained person who meets with providers in their practice settings to provide information with the intent of changing the provider's performance. The information given may include feedback on the provider's performance

Effectiveness. A measure of the benefit resulting from an intervention for a given health problem under usual conditions of clinical care for a particular group.

Efficacy. A measure of the benefit resulting from an intervention for a given health problem under the ideal conditions of an investigation

Evidence-based medicine. The conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research.

External validity. The extent to which a causal relationship holds over variations in persons, settings, treatments, and outcomes.

Implementation. Execution of a plan, e.g. by taking actions to change clinical policy or practice in line with a clinical guideline.

Implementation research. Research which aims to inform policy decisions about how best to use resources to improve the uptake of research findings by testing approaches to change professional and organisational behaviour.

Intention to treat analysis. A method for data analysis in a randomized clinical trial in which individual outcomes are analyzed according to the group to which they have been randomized, even if they never received the treatment they were assigned

Interactive educational meetings. Participation of health care workers in workshops that include discussion or practice

Internal validity. The validity of inferences made about whether an intervention causes an outcome.

Intervention. A programme or treatment carried out, usually with the aim of improving outcomes.

Intra-cluster correlation (ICC). A statistical measure of the degree of similarity of outcomes observed within any one group (e.g. a clinical team or hospital).

Local consensus process. Inclusion of participating health care workers in discussion to ensure that they agreed that the chosen clinical problem was important and the approach to managing the problem was appropriate

Local opinion leaders. Use of health care workers nominated by their colleagues as 'educationally influential'

Logistic regression. A statistical method used to investigate the relationship between an event rate or proportion and a set of independent variables.

Meta-analysis. An overview which uses quantitative methods to summarise the results.

Multifaceted interventions. A combination two or more interventions

Null hypothesis. The null hypothesis states that the results observed in a study are no different from what might have occurred as a result of the play of chance.

Number Needed to Treat (NNT). The number of patients who need to be treated to prevent one bad outcome.

Odds ratio. The ratio of the odds of an event in the experimental (intervention) group to the odds of an event in the control group.

Overview. A systematic review and summary of the health care literature.

Patient mediated interventions. Any intervention aimed at changing the performance of health care providers where specific information was sought from or given to patients

Randomized controlled trial. A study design where treatments, interventions, or enrollment into different study groups are assigned by random allocation. In cluster randomised trials groups of participants are allocated to different interventions.

Recall bias. Systematic error due to the differences in accuracy or completeness of recall to memory of past events or experiences.

Reminders. Any manual or computersied intervention that prompts the health care provider to perform a patient specific clinical action

Reproducibility (repeatability, reliability). The degree to which results of a test or measure are identical or closely similar each time it is conducted.

Selection bias. A bias in assignment or a confounding variable that arises from study design rather than by chance. These can occur when the study and control groups are chosen so that they differ from each other by one or more factors that may affect the outcome of the study.

Statistical conclusion validity. Whether there is a true association between an intervention and outcome and, if so, the strength of that association

Statistical power. The probability that the null hypothesis will be rejected if it is indeed false.

Stratification. Division into groups. Stratification may also refer to a process to control for differences in confounding variables, by making separate estimates for groups of individuals who have the same values for the confounding variables.

Theory of Planned Behaviour (TPB). A motivational theory which proposes that individual behaviour is primarily determined by the strength of an individual's intention to perform that behaviour.

Time series analysis. The use of multiple observations before and after an intervention, attempting to detect whether an intervention has had an effect greater than any underlying trends in outcomes.

Uncontrolled before-and-after study. A study in which observations are made in one group before and after an intervention and observed differences assumed to be due to the intervention.

Unit of analysis error. The erroneous analysis of a study whereby individuals allocated by groups are analysed as if they had been allocated individually. This can result in overly narrow confidence intervals and false positive conclusions that an intervention has had an effect.

Validity. The extent to which a variable or intervention measures what it is supposed to measure or accomplishes what it is supposed to accomplish.

Variance. A measure of the variation shown by a set of observations, defined by the sum of the squares of deviations from the mean, divided by the number of degrees of freedom in the set of observations.

Abbreviations

CEMD	Confidential Enquiries into Maternal Deaths
CHI	Commission for Health Improvement
CI	Confidence interval
CRAG	Clinical Audit and Resource Group
CSBS	Clinical Standards Board for Scotland
CSO	Chief Scientist Office
D&C	Dilatation and curettage
GAPS	Gynaecology Audit Project in Scotland
HTBS	Health Technology Board for Scotland
ImpACT	Improving Abortion Care Trial
ISD	Information and Statistics Division
IQR	Inter-quartile range
NICE	National Institute for Clinical Excellence
OR	Odds ratio
ORACLE	MRC Preterm Antibiotic Uncertainty Study
PBC	Perceived Behavioural Control
PPROM	preterm pre-labour rupture of the membranes
RCM	Royal College of Midwives
RCOG	Royal College of Obstetricians and Gynaecologists
SD	Standard Deviation
SEHD	Scottish Executive Health Department
SHO	Senior House Officer
SIGN	Scottish Intercollegiate Guidelines Network
SOGAP	Scottish Obstetric Guideline and Audit Project
SPCERH	Scottish Programme for Clinical Effectiveness in Reproductive Health
SPSS	Statistics Package for Social Sciences
SSBIDS	Scottish Stillbirth and Infant Death Survey
TPB	Theory of Planned Behaviour

Chapter 1

Introduction

1.1 Summary

The transfer of valid and relevant research findings into routine practice is unpredictable and tends to be a slow and haphazard process. This problem occurs across different healthcare settings, countries and specialities. Health care systems are under increasing pressure to implement evidence-based care and reduce inappropriate care. Three broad approaches have proposed to help achieve these goals: the dissemination of rigorously developed clinical guidelines to inform health care practice and policy; the identification and use of effective implementation strategies; and the creation of the right organisational conditions for change. This chapter discusses the role of these approaches in promoting evidence-based care, highlighting current knowledge and research needs.

Launched in 1997, the Scottish Programme for Clinical Effectiveness in Reproductive Health (SPCERH) was given the over-arching goal: to improve health outcomes for women and their families throughout Scotland by promoting more uniform standards of high quality, evidence-based reproductive healthcare. SPCERH's work plan included a programme of research evaluating the effectiveness of its dissemination and implementation strategies. This chapter introduces that programme and sets out the related research objectives that form the basis of this thesis.

This chapter is partly based upon the following papers

Foy R, Walker A, Penney GC. Barriers to clinical guidelines: the need for concerted action. British Journal of Clinical Governance 2001;6:166-174.

Foy R, Eccles M, Grimshaw J. Why does primary care need more implementation research? Family Practice 2001;18:353-5.

1.2 The gap between evidence and practice

1.2.1 Inappropriate variations in health care

Clinical research continually produces new findings that can contribute to effective and efficient patient care. However, such research cannot change patient outcomes unless health services and health care professionals adopt them in practice. Pioneers of evidence based medicine recognised frequent failures of the medical profession to base practice on scientific evidence (1). Sometimes, this is represented by delays in compiling and appraising research findings in a systematic fashion (2). More commonly, there are failures to act upon evidence.

The introduction of antenatal corticosteroids to prevent neonatal respiratory distress syndrome illustrates a delay in uptake of valid research findings. A meta-analysis of randomised controlled trials published in 1990 demonstrated a 70% relative reduction in mortality for infants born before 31 weeks gestation when corticosteroids were administered for 24 hours or more before delivery (3). A Scottish audit assessed care received by 1601 such infants among nine hospitals over 1988-93 (4). Before publication of the meta-analysis, 16% of their mothers had received antenatal steroids for 24 hours or more; only 29% received steroids within the four year period following publication.

Ineffective or inefficient clinical practices may continue despite evidence demonstrating lack of benefit. Dilatation and curettage (D&C) was commonly used in the investigation of abnormal endometrial bleeding. A report of a systematic review and a Royal College of Obstetricians and Gynaecologists (RCOG) report recommended that: 'D&C should not be performed in women aged under 40 and its use in older women could be replaced by cheaper and safer methods of endometrial sampling' (5;6). A subsequent audit of practice across 12 hospitals in Scotland found that D&Cs comprised 21% of endometrial sampling procedures and that 23% of women undergoing endometrial sampling procedures were under 40 (7).

Inappropriate variations in care occur across different healthcare settings, countries and specialities (8-14). Studies have been unable to explain this variation in terms of either patient or resource factors. Accepting that variation alone does not necessarily represent inappropriate care a small number of studies have gone on to assess appropriateness and conclude that inappropriate care delivery was occurring (14). The UK NHS is under mounting pressure to reduce inappropriate variations and improve the quality of care from successive governments impatient for results.

1.2.2 Factors that influence the implementation of evidence-based practice

Several frameworks have been used to describe factors that may promote or hinder the implementation of evidence-based practice (15-20). One approach describes barriers under three main categories related to the nature of the evidence or change itself, the characteristics of the individuals who need to change, and the characteristics of the organisation or environment (21). Tables 1.1 to 1.3 demonstrate the range of barriers to change, accompanied by illustrative examples largely related to reproductive health care. The framework is not presented as a theoretically-based taxonomy and some of the distinctions among barriers appear arbitrary.

Table 1.1. Barriers to change related to the nature of the evidence or change itself.

Barrier	Example
Validity	
Poor quality of evidence	Poorer quality studies assessing diagnostic tests may over-estimate their accuracy by up to three-fold (22)
Insufficient quality control in clinical guideline development process	Failure to make explicit link between recommendations and supporting evidence in 18% of medical society guidelines published over 1988-98 (23)
Relevance	
Limited applicability to clinical practice related to differences in or inadequate description of population (24)	Use of magnesium sulphate to prevent fits in pre-eclampsia despite lack of clear evidence of benefit (25)
Limited applicability to clinical practice related to unavailability of or inadequate description of interventions	Wider use of hysterosalpingography (HSG) as first line in the investigation of infertility limited by availability of appropriately trained radiologists (26)
Uncertainty about the durability ('shelf-life') of new research evidence (27)	Variation in the use of agents to prevent or delay active preterm labour because of evolving evidence about optimal choice of agent and regimen and selection of women most likely to benefit.
Unavailability of direct evidence to answer clinically important questions	Lack of data indicating likelihood of myocardial infarction for young, low-risk women using combined oral contraception (28)
Practicality	
Imprecise or ambiguous wording of guideline recommendations (29)	Ambiguity of recommendations to investigate 'post-menopausal bleeding' because of varying criteria to diagnose menopause
Disruption to routine practice (29)	Need for changes in organisation of services to introduce medical abortion service
Low awareness of information sources or unavailability of evidence at point of need (30)	Limited or no access to Cochrane Reviews, (31;32)
Attainment of "ceiling effects," beyond which it is difficult to change practice further	Lack of improvement in compliance with selected recommendations from Cochrane Reviews (33)

Table 1.2. Barriers to change related to characteristics of the individuals who need to change.

Barrier	Example
Knowledge	
Lack of awareness that clinical practice may be inappropriate	Prescribing of ineffective drug therapy for endometriosis-related infertility (34)
Over-reliance on trusted or convenient sources of information (35)	Seeking advice from colleagues or specialists without questioning evidence base (36)
Over-estimation of self-reported performance, (37) or perceived irrelevance to practice (38)	Over-estimation of actual use of corticosteroids to prevent complications following preterm labour (31)
Attitudes and beliefs	
General hostility to guidelines (39)	Fears that introduction of guidelines increases susceptibility to litigation or reduces scope for using clinical judgement (40)
Previous adverse experience of changing practice (41)	Experience of fetal death following use of external cephalic version in management of term breech (42)
Doubts over credibility of source or change agent (43-45)	Rejection of patient information leaflet by midwives and ultrasonographers because of disagreement with its assessment of costs and benefits of routine ultrasound screening (43)
Hostility to challenges to established practices, including those where research has been outpaced by development (46)	Routine use of intra-partum cardiotocography (CTG) despite doubts over the evidence base (47)
Low outcome expectation, i.e. belief that following recommendation will not lead to expected outcome (39)	Perceived low 'returns' on preventive measures such encouraging smoking cessation in pregnancy
Avoidance of recommendations because of perceived increased susceptibility to litigation	Over-investigation and management of women with mild hypertension in pregnancy because of concern about missing severe hypertension (48)
Not sharing information with patients because of perceived resistance or demands (30) or concern about raising anxiety	Ultrasonographers' 'protection' of women from information about the potential harms of antenatal ultrasound, e.g. abnormal scan result leading to abortion of normal fetus (43)
Skills and capacity	
Lack of skills and time to undertake brief targeted searches for clinical evidence or guidelines (49)	Undertaking apparently simple but time-consuming Medline searches (30)
Lack of skills in critical appraisal (of clinical guidelines as well as original research) (27;30)	Over-estimation of benefits or risks from interventions when relative risk reduction is used (50), e.g. 'risk of transfusion at time of abortion doubles for every 2 week increment in gestation' (51), fails to convey absolute risk of only 2/1000 and relative safety of abortion procedure
Lack of self-efficacy (i.e. ability or means to perform a task) (39)	Infrequent enquiry into domestic violence during antenatal consultations by midwives or obstetricians because of concerns about counselling skills (52)
Limited capacity of professionals to process all relevant information in clinical practice, especially during high pressure situations (53)	Complexity of and inherent uncertainty in assessment of fetal distress during labour

Table 1.3. Barriers to change related to characteristics of the organisation or environment.

Barrier	Example
Established approaches to change	
Over-reliance on passive methods of dissemination (54;55)	Passive dissemination of Report of Confidential Enquiries into Maternal Deaths and resulting low awareness of key recommendations among obstetricians and midwives (52)
Poor targeting of clinical guidelines	Inability of professionals and organisations to cope with proliferating quantities of clinical guidelines (56;57)
Clinical guidelines 'adopted' without consensus or adaptation to local circumstances (58)	Imposition of national guidance without consultation – such as the requirements for 'approval of independent sector places for the termination of pregnancy' by the Secretary of State for Health (51)
Competing priorities and organisational inertia	
Failure to prioritise implementation (59)	Lack of resources for implementation relative to the production of evidence (31)
Managing the complexity of adopting desired practice (29;44)	Organisation of multi-disciplinary care and follow-up for women with gynaecological cancer (60)
Culture	
Little or no history of multidisciplinary working (38)	Resistance to expanded role for gynaecology nurses delaying the introduction of medical abortion services
Negative attitudes from colleagues or other professionals towards challenging existing practices or reinforcing new effective practices (30) (41)	Resistance to adoption of routine antibiotic prophylaxis at Caesarean section despite Cochrane Review demonstrating effectiveness (61)
Constraints of hierarchical relationships	Midwives' support for Informed Choice patient information leaflets compromised by obstetrician preferences (62)
Constraints of normative values	Range of choices in maternity care, highlighted by for Informed Choice patient information leaflets, limited by local availability and values (62)
Abdication or avoidance of organisational responsibility	Tendency for internal reviews of medical errors to focus on individual rather than organisational factors (63).
Resources	
Lack of protected time and resources to plan changes in practice (38;64) (39)	Continuing use of intensive schedules of antenatal care, with duplications of care by obstetricians, GPs and midwives, despite evidence that reduced-visit schedules do not compromise safety and that many women can be cared for by GPs and midwives alone (65;66)
Diluted or non-implementation of proven interventions because of limited resources (67)	Rationing of in-vitro fertilisation (68)
Opportunity costs of evaluating and changing performance	Establishment of guideline initiatives without explicit link to audit
Knowledge and assessment of organisational performance	
Marginalisation of clinical audit	Concerns over perceived threats to professionals, restriction of clinical freedom and increased workload (69;70)
Absence or poor quality of clinical audit (44)	Insufficient resources to support audit and lack of expertise in its conduct (69)
Difficulty in measuring or interpreting outcomes (71)	Unreliability of in-vitro fertilisation league tables in assessment of units' performance because of year-on-year random variation and biases in presentation of results (72;73)
Short term outlook rather than appreciation of long term nature of achieving and sustaining change (38)	Traditional short-term project funding of audit and guideline exercises (74)
Patient preferences	
Conflicting patient knowledge, expectations and preference over choices in clinical management (43)	Demand for caesarean section in the absence of medical indications (75)

Some barriers are deeply entrenched whilst others are more amenable to change. Furthermore, many factors categorised under barriers may also promote evidence-based practice. To date, the knowledge and expectations of patients have mainly been identified in the research literature as a barrier. However, informed patients may facilitate rather than impede more appropriate care in some circumstances (76).

Professionals and policy-makers have responded to these barriers in a number of ways. These responses have included the development and dissemination of clinical guidelines, the use of effective implementation strategies, and the optimisation of organisational conditions for change. The following sections (1.3 to 1.5) discuss the relevance of these three factors to evidence-based care, highlighting current knowledge and research needs.

1.3 The need for rigorously developed clinical guidelines

Clinical guidelines are increasingly being used guide clinical practice and policy (77). Clinical guidelines have been defined as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" (78). The potential benefits of clinical guidelines need to be balanced against their potential costs and limitations (79).

1.3.1 Potential benefits, costs and limitations of guidelines

Improving outcomes. Potential health benefits from following recommendations include reduced mortality, improved health-related quality of life, reassurance and avoidance of unnecessary procedures. The validity of guideline recommendations is critical, i.e. 'when followed they lead to the health gains and costs predicted for them' (78). Clinical guidelines therefore need to be developed using a rigorous methodology, including:

- The participation of professionals with expertise in the clinical topic, literature searching, epidemiology, health services research, facilitating group processes and writing – as well as other stake-holders, such as service user advocates (80)
- A comprehensive search to identify relevant research
- Linking of recommendations to reviewed evidence
- Explicit consideration of other factors in grading of recommendations, including the relevance of the evidence to the target population, economic considerations, values of the guideline developers and society, and practical issues concerning implementation (81).

- Clearly defining where and when the guideline can be applied, e.g. according to the availability of requisite skills or resources

An analysis of guidelines produced by specialty societies over 1988-98 demonstrated that the majority failed to meet a range of criteria for good quality, such as explicit grading of evidence (23). Guidelines are more likely to be valid if produced by national or regional guideline development groups according to rigorous and explicit methods (82). Within the UK, the Scottish Intercollegiate Guidelines Network (SIGN) has been developing expertise and experience in guideline development (83). The National Institute for Clinical Excellence (NICE) in England and Wales now also undertakes a similar role.

Coping with information. Health professionals work in an age of information overload and increasing complexity of care. The production rate of new clinical evidence can overwhelm even the most committed professional in any field (30;84). Given the burdens associated with assimilating information from individual studies and the growing volume of systematic reviews, guidelines can provide relevant and reliable summaries of clinical evidence.

Indiscriminate distribution of guidelines may cause alienation if clinicians are overwhelmed by proliferating quantities of guidelines (56). In one survey, 45 different guidelines for the management of depression in primary care were identified within the UK (85). There was a considerable range in the quality of a subset of guidelines appraised in detail. Rather than promoting uniform standards of care, the growth in the number of guidelines risks perpetuating variations in practice.

Risk management. Guidelines can help professionals reduce or cope with clinical uncertainty by explicitly balancing known benefits and risks. Whilst the avoidance of litigation is often associated with taking additional actions (e.g. an investigation), it is often necessary to define thresholds below which action is unlikely to produce clinical benefit. Defensive medicine has been said to be rooted in the syndrome of "nominators looking for denominators" (86). Recent clinical experience of a stillbirth may inappropriately but understandably lower the threshold at which an obstetrician would advise caesarean section in subsequent deliveries. Guidelines can help reduce inappropriate practice without compromising standards of care. For example, in a high risk specialty such as obstetrics, guidelines may aim to reduce the caesarean section rate by promoting a trial of labour in women with a previous caesarean section (87) or reduce inappropriate investigations and hospital admissions associated with mild, non-proteinuric hypertension (48).

There is confusion as to whether the adoption of guidelines and pathways increases or decreases vulnerability to litigation (88). On one hand, there is concern that clinicians who fail to follow guidelines or pathways will be accused of falling short of acceptable standards. On the other, the implementation of guidelines may lead to safer and more effective care, thereby reducing clinical risk. There is no direct evidence that the introduction of guidelines has contributed to increased rates of litigation, particularly from the United States where there is greater experience of guidelines. Guidelines have been cited as evidence in 6% of a random sample of case in claims opening over 1990-91, in roughly equal proportions for the plaintiff and defendant (89).

Resource allocation. There are two main costs associated with clinical guidelines. Firstly, there are costs related to the development of the guideline and the measures (if any) taken to support their dissemination and implementation (e.g. educational activities). Secondly, there are costs (or savings) subsequent to putting recommendations into practice (e.g. increased or decreased prescribing)(90). In some circumstances, the opportunity costs of guideline development, dissemination and implementation may outweigh potential benefits.

Resources available for health care are limited. Policy makers, managers and clinicians need relevant and reliable evidence to inform resource allocation. Ideally, the evaluation of new health care technologies incorporates an assessment of cost-effectiveness. If cost-effectiveness data are unavailable, guideline developers need to take account of approximate relative costs in presenting their recommendations (81).

Rigorously developed guidelines can highlight under or over provision of certain services. Yet, as well as encouraging fairer resource allocation, the adoption of guidelines may also promote the inappropriate provision of health care interventions or facilities. Guideline developers therefore need to consider the wider implications and possible unknown costs and consequences of their recommendations (91;92).

Shared decision-making. There is a growing emphasis on enhanced patient involvement in decisions relating to their care. Some guidelines are produced with 'lay' versions to promote more consistent patient education, especially for chronic conditions which require a substantial degree of self care. In addition, patients can use guidelines to prompt clinicians to reconsider or change aspects of their care.

Guidelines tend to apply to a group of patients as a whole. There is a persistent perception that guidelines restrict individual choice (39). Individuals may receive inappropriate care if recommendations are poorly worded or interpreted without reference to individual clinical needs

and preferences. Patient clinical needs may be compromised, for example, if clinicians following guidelines on the management of hypertension are unaware of their limitations and fail to take into account pre-existing illnesses and risk factors that might complicate treatment and modify outcomes (93). Patient preferences may bring them into conflict with the guidelines and clinicians attempting to follow them, especially where a preference is expressed for ineffective or less cost-effective options. As discussed above, health care resources are limited and guideline development usually needs to favour more cost-effective treatment options. Setting limits within guidelines to reflect what health care systems will pay for may reduce conflict between clinicians and patients (94). Subsequently, the conflict may shift to one between patients (possibly with their clinicians) and the health care system.

1.3.2 Determining the need for a guideline

Given the opportunity costs associated with developing or adopting guidelines, organisations need criteria against which to judge the need for a guideline, such that the likely benefits of implementation outweigh probable costs (95). The choice of topic is often determined by locally or nationally set priorities. The criteria for selecting a topic may reflect evidence of inappropriate clinical care, scope for preventing mortality or morbidity, or opportunities to improve the efficiency of care.

Once a topic has been agreed, local clinicians and managers have the option of either developing a new guideline themselves or adapting one already developed, usually at a national level. As most health care organisations lack the resources (especially in terms of professional time) required to develop new guidelines from scratch, it is usually expedient and probably more efficient to draw upon pre-existing guidelines. Checklists are available for the critical appraisal of guidelines not already reviewed by bodies such as SIGN or NICE (96). Local adaptation usually requires input from a multidisciplinary team, similar in composition to that of the original guideline development group. Guidelines can be adapted to reflect local circumstances, such as the availability of services or patient characteristics. There is scope for changing recommendations based upon weak evidence but changing those based on good evidence requires explicit justification (95).

1.3.3 Guidelines and changing practice

Implementation of valid guidelines can improve clinical practice, especially if effective dissemination and implementation strategies are used (58). Other factors, or effect modifiers, can influence the effectiveness of such strategies (97). Until recently, most research has focused on characteristics of clinicians or health care organisations, such as local attitudes or preparedness to

change. However, the characteristics (or attributes) of clinical practice recommendations themselves may also influence their rate of adoption (98). Higher or lower compliance may be associated with certain attributes, e.g. those that are compatible with clinician norms and values or disruptive to routine practice (29;99).

Previous work focused on the effects of various attributes on *compliance* with recommendations (i.e. a one-off measure of performance). However, clinical guidelines are produced to promote *change* in behaviour, which may be influenced by attributes different from those associated with compliance. Less is known about whether various attributes of clinical practice recommendations influence both compliance and change in clinical behaviour (Chapter 2).

1.4 The need for effective strategies to change professional practice

1.4.1 Existing strategies

A range of strategies exists to change professional behaviour and promote evidence-based health care (Table 1.4, overleaf). These strategies are often designed to overcome barriers associated with individual professional (Table 1.2) or organisational factors (Table 1.3). Strategies may encompass professional interventions (e.g. continuing medical education, audit and feedback), financial interventions (e.g. professional incentives), organisational interventions (e.g. the expanded role of pharmacists) or regulatory interventions (e.g. professional accreditation). The interventions are broadly based upon a range of theoretical approaches and assumptions about how individuals and organisations behave. The challenge for those harnessing such interventions to improve the quality of care is how to ensure their selection is based more upon evidence than on belief (100).

1.4.2 Lessons from systematic reviews

As with clinical care, systematic reviews of rigorous studies have greatly contributed to knowledge about what works in changing professional and organisational behaviour. An overview of systematic reviews (101) suggested that it was possible to identify strategies that were more, or less, effective. Strategies such as postal distribution of guidelines or didactic educational sessions were suggested to be largely ineffective. Local consensus conferences, the use of opinion leaders or audit and feedback were of variable effectiveness. Interactive educational workshops, reminder systems, educational outreach and multi-faceted interventions were suggested as largely effective.

Table 1.4. Examples of interventions to promote professional behavioural change (102).

Educational outreach visits – Use of a trained person who meets with providers in their practice settings to provide information with the intent of changing the provider's performance. The information given may include feedback on the provider's performance
Reminders (manual or computerised) – Any intervention that prompts the health care provider to perform a patient specific clinical action
Multifaceted interventions - A combination two or more interventions
Interactive educational meetings - Participation of health care providers in workshops that include discussion or practice
Audit and feedback - Any summary of clinical performance
Local opinion leaders - Use of providers nominated by their colleagues as 'educationally influential'
Local consensus process - Inclusion of participating providers in discussion to ensure that they agreed that the chosen clinical problem was important and the approach to managing the problem was appropriate
Patient mediated interventions - Any intervention aimed at changing the performance of health care providers where specific information was sought from or given to patients
Educational materials - Distribution of published or printed recommendations for clinical care, including clinical practice guidelines, audio-visual materials and electronic publications
Didactic educational meetings - Lectures

Closer scrutiny of these findings by a recent systematic review highlights major weaknesses in the evidence base (103). This review represents the most comprehensive systematic review to date, including 235 studies comparing a total of 309 interventions. It challenges previous views about the effectiveness and transferability of interventions to improve practice. For example, there is no direct evidence that combinations of interventions are more effective than single interventions, and simple dissemination of educational materials may be as effective as more active methods. Effect sizes tend to be relatively small or modest and are sometimes of uncertain clinical impact. However, interpretation was frequently hindered by the poor methodological quality of primary studies.

The evidence for effective interventions may not stand up to the real world of local implementation because of doubts over transferability. First, there is uncertainty over what factors are important in the relative success or failure of reported strategies because of the lack of an established theoretical framework. Second, studies do not measure or report potential effect

modifiers. Systematic reviews indicate variable effectiveness within the same interventions, such as audit and feedback or use of local opinion leaders (people identified as being educationally influential by their peers). These variations might be attributable to the modifying effects of context and content. The feasibility of identifying local opinion leaders and their potential effectiveness are often compromised by the variability and idiosyncrasies of local professional networks (104). Inconsistent findings might also be explained by variations in the intensity or quality of the interventions tested. Third, interventions are often poorly described – thus posing a problem for aggregation within systematic reviews and for subsequent interpretation in order to reproduce successful interventions. Although prompts and reminders appear to be consistently effective, their frequency and proximity to the point of clinical decision-making may influence the size of their impact.

Interventions to overcome specific barriers should ideally be tailored to the nature of anticipated local problems (100). There is a growing body of evidence to support the prior assessment of barriers and needs (55). Theoretical models of change can be used both to understand the behaviour of health professionals and organisations and to guide the development of interventions to promote change (101;105). These theories are derived from a range of disciplines (e.g. applied psychology, management studies) and generally apply to different levels of change, i.e. those of individual professionals, teams and organisations (18). Ultimately, the aim is to develop an empirical basis for selecting interventions given specific barriers and circumstances.

Where effectiveness is consistently demonstrated, it is often difficult to judge whether benefits are outweighed by costs. Few studies have assessed the direct costs of changing clinical behaviour, not to mention the indirect effects on health services following implementation strategies (103). Resources are limited and any implementation strategies that exhaust these limited resources will not be sustainable in the long term. Those responsible for local implementation need to know as much about the cost-effectiveness of behavioural interventions as they do about that of clinical interventions.

1.5 Optimising organisational conditions for change

1.5.1 The influence of organisational factors

There is growing recognition of the influence of organisational culture upon the behaviour of health care professionals and providers (106). Organisational culture has been defined as "a set of tacit assumptions about how the world is and ought to be that is shared by a set of people and

determines their perceptions, thoughts, and feelings and, to some degree, their behaviour" (107). Strategies to change or regulate an organisation's behaviour are complicated by and need to take account of its established norms and values. Changing organisational culture requires substantial political leadership and a marked shift in how members of an organisation perceive themselves (18). The advent of clinical governance in the UK NHS represents an attempt to change organisational culture and bring together a range of quality improvement methods to improve health care.

1.5.2 Clinical governance

Clinical governance has been defined as "a system through which UK National Health Service organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish" (108).

Origins and scope. A series of events late in the 1990's undermined public confidence in the NHS. Concern about 'rationing by postcode' highlighted the need to tackle inequity of health care provision. More alarmingly, systematic failures in the organisation and provision of care became apparent, notably during the inquiry into paediatric cardiology at Bristol Royal Infirmary (109). The specialty of obstetrics and gynaecology has also remained prone to adverse publicity, e.g. following consultant suspensions for professional misconduct and discoveries of scientific fraud (110-112). Against this background, the incoming Labour government was looking for a 'big idea' to spearhead its efforts to reform the NHS (113).

The 1997 White Paper, *The new NHS*, announced the establishment of new mechanisms and structures to improve quality (114). The National Centre for Clinical Excellence (NICE) was established to appraise and disseminate advice on new and existing treatments whilst National Service Frameworks set out common standards for major clinical areas. Clinical governance emphasised the local arrangements to ensure that national standards for clinical care were met; it therefore united previous clinical audit (115) and effectiveness initiatives (116) with more explicit procedures for managing and dealing with clinical risk and poor performance.

The impact of these earlier initiatives had been undermined by significant organisational shortcomings. Firstly, clinical audit often appeared to be an ad hoc activity led by clinicians in isolation from the rest of the organisation (and sometimes even from their peers) (70). There was a lack of a broader framework to ensure that the emphasis of clinical audit shifted from measuring performance and providing small amounts of feedback towards changing practice. Secondly, the dissemination of clinical guidelines and rapid expansion in the availability of other

paper and electronic sources of information were seldom accompanied by active local implementation. Thirdly, management-led initiatives had mainly remained concerned with resource use. The advent of the 'internal market' for health care had concentrated senior management's attention on financial control and marginalised clinical issues from NHS board agendas - unless provoked by adverse events or calls for more resources.

Critically, under clinical governance, chief executives of NHS organisations were given ultimate responsibility for assuring the quality of services, just as they were previously accountable for the proper use of resources. Organisations appointed clinical governance boards with a central role in monitoring and improving local standards of care. A designated senior clinician became responsible for ensuring that the appropriate systems were in place. The Commission for Health Improvement (CHI) was constituted to act as a watchdog over local clinical governance arrangements and become involved in trouble-shooting if necessary.

The detail of arrangements differed in Scotland although the overall policy thrust remained similar. Two key bodies were already in place. The Clinical Resource and Audit Group (CRAG) initially led efforts to promote clinical effectiveness. The Scottish Intercollegiate Guidelines Network (SIGN) represented a professionally led initiative for the development and dissemination of clinical guidelines. The Scottish White Paper, *Designed to Care*, set up the Health Technology Board for Scotland (HTBS) to appraise and provide guidance on new and established health technologies, fulfilling an analogous role to NICE (117). The Clinical Standards Board for Scotland (CSBS) was established to monitor and support local implementation, albeit without the explicit watchdog function of CHI.

Challenges to clinical governance. On top of professional cynicism at the prospect of another quality initiative (118), getting the principles of clinical governance into practice posed major challenges. Assessing clinical and organisational performance is problematic (119;120) and dissemination of such data may have unintended consequences (72;73;121;122). Much of the focus and remedial actions to tackle poor performance have tended to focus on selected individuals, teams or even hospitals (123). These occur at the expense of considering the wider environments in which they exist (63) and despite recognition by the Department of Health of the need to move away from a 'blame culture' (124). Cultural gaps remain between health care management and health (most frequently, medical) professionals (18). Some of this gap has been bridged by clinicians' greater adoption of managerial responsibilities - although the wider body of clinicians may still perceive colleagues in management as relative outsiders.

As well as representing a new template for NHS organisational culture, clinical governance entails the integration of a variety of approaches to improving health care, e.g. clinical audit, continuing professional development. Grol contends that the choice of interventions to promote clinical effectiveness is currently as likely to be based on habit and belief rather than convincing evidence of effectiveness (100). However, as highlighted above (section 1.4.2), better evidence is needed to help identify effective and efficient strategies to promote good practice.

1.6 Implementation research

Implementation research aims to inform policy decisions about how best to use resources to improve the uptake of research findings by testing approaches to change professional and organisational behaviour. Rigorous designs and methods are needed to allow valid and reliable estimates of the likely effects of alternative interventions to be made (125). The validity and relevance of research methods will be addressed throughout this thesis.

1.6.1 Measuring effectiveness

The validity and relevance of effectiveness data depend upon what is measured, the timing of measurements and how measurements are taken. Measures of effectiveness can include changes in health outcomes, such as complication rates or patient quality of life, or health care process outcomes, such as compliance with guideline recommendations. Measuring health outcomes generally results in the problems of prohibitive sample sizes, longer time scales and greater expense associated with detecting clinically significant effects. Measures of process are more sensitive than health outcome measures in detecting differences in the quality of care (126). Implementation research tends to focus on tracer activities that reflect the overall quality of care (127;128). The key assumption is that the validity of the recommendations followed or changes made is proven, thus negating any need to measure actual health outcomes.

The timing of measurements is relevant to the planning of studies and assessment of outcomes (125). Measurements of baseline (or pre-intervention) performance inform sample size calculations, allow comparisons to be made between intervention and control groups, and help assess the magnitude of any changes in performance. The timing of measuring outcomes at follow-up (post-intervention) requires careful consideration. If measured too soon, outcomes associated with learning effects or more complex organisational changes may not be detected. It is also possible that interventions may have significant but unsustained effects that later measurements may fail to detect, e.g. improved compliance from raised awareness of a

recommendation following an educational programme. Ideally, change over time should be measured to identify such effects and quantify their influence.

How outcomes are measured influences their validity. Surveys of professionals may be useful for testing by testing simple aspects of guideline dissemination, such as receipt by target users and availability. However, compared with more objective measures, self-reports of activity tend to overestimate actual performance (37;129). Other methods of data collection may also sensitise professionals to desired practice. For example, the collection of structured data by professionals participating in a study may improve performance by itself. Intrusive data collection may lead to improved performance in both intervention and control groups, potentially underestimating the effect of the intervention. Data collection should aim to be minimally intrusive. Where possible, researchers should consider using routinely collected data, such as from case notes, in order to reduce sensitisation.

1.6.2 Study designs

As with the testing of clinical interventions, randomised evaluations of interventions to change professional and organisational behaviour produce the least biased estimates of effect. However, well-designed non-randomised studies can still provide robust evidence where there are practical and ethical barriers to conducting randomised studies (130). Following this brief outline, the strengths and weaknesses associated with different methods of measuring outcomes and study designs will be explored in detail under the separate studies contributing to this thesis.

Case studies describing the process of change in single groups can provide insights into factors that influence change and generate hypotheses for further testing in rigorous evaluations, especially if qualitative methods are applied. Some evaluations draw on a series of case studies to explore factors that may promote successful organisational change (131). No causal inferences can be made.

After studies. Observations are only made following an intervention, sometimes in more than one group of professionals (132). Because observations are not made before the intervention, it is not certain that the intervention has resulted in any change. The lack of a control group means that no allowance can be made for secular trends.

Uncontrolled before-and-after studies. Observations are made in one group before and after an intervention and observed differences assumed to be due to the intervention (133). The advantage of this design is that many characteristics of the study population may be similar when both measurements are taken. There are several problems in attributing any changes in outcome

to the intervention. First, regression to the mean occurs when study units selected on the basis of their extreme scores (e.g. low compliance with guideline recommendations) subsequently tend to give scores closer to the average. Second, maturation occurs when the passage of time brings about changes in the study units independent of the intervention. For example, clinicians may become more familiar with a guideline and practising its recommendations over time and this may be unrelated to the intervention. When measuring outcomes over time changes in the definition or measurement of an outcome may change over time or (in questionnaire surveys) professionals may become sensitised to the most appropriate responses.

Controlled before-and-after (CBA) studies. This design strengthens before-and-after studies by incorporating a non-randomised control group that will experience trends and changes similar to those of the study group. Data are collected in both groups before and after the intervention is applied to study group. Differences in performance between the study and control groups following the intervention are assumed to be due to the intervention. The need for similar baseline characteristics and performance can make it difficult to find appropriate control groups, e.g. with similar organisational characteristics and patient case mix. It is possible to assess change from baseline performance where baselines differ but the very existence of baseline imbalances suggests that a control group is not similar in other important respects (that can modify effectiveness of any intervention tested). The non-randomised nature of CBAs therefore risks residual selection bias. Regression to the mean may also complicate interpretation of findings if participating study sites are (partly) selected on the basis of extreme scores.

Time series analyses entail the use of multiple observations before and after an intervention, attempting to detect whether an intervention has had an effect greater than any underlying trends in practice (134). Time series analyses may be used in estimating the effects of mass media campaigns, legislation or dissemination of national guidelines. They therefore tend to be opportunistic (135). Simple (uncontrolled) time series analyses allow for secular changes resulting from maturation or regression to the mean to be estimated. Potential sources of bias remain. External events, in addition to the intervention, may influence outcomes. Secular changes in instrumentation, the way outcomes are measured, may occur. Controlled time series analyses can enhance validity by including a control group to allow for more rigorous control of external influences (76). As with other non-randomised studies, potential sources of bias may stem from the selection of study units or regression to the mean.

Randomised trials aim to counter many of the aforementioned biases and represent the most rigorous available design for evaluating interventions (125;132;136;137). Randomisation by individual is inappropriate for interventions taking place at an organisational or geographical

level, largely because of contamination effects (138). In cluster randomised trials groups of participants are allocated to different interventions. Cluster randomisation has major implications for design and analysis (125;132). Firstly, randomisation should occur at a level that minimises potential contamination, e.g. at clinician, unit or hospital levels. Secondly, patients within any one cluster are more likely to have similar outcomes – statistically measured by the intra-cluster correlation (ICC). Hence standard statistical analyses assuming that the outcome for one patient would be independent of another no longer hold. Subsequently, larger sample sizes are required with analysis at or accounting for the cluster as the unit of randomisation. Previous studies have often ignored important methodological issues, in particular accounting for clustering effects (139).

The designs of cluster randomised trials can be strengthened. For example, in balanced incomplete block designs, each participating professional experiences both the new intervention and the *status quo* simultaneously for two or more clinical conditions (140). This design equalises Hawthorne and other non-specific effects across both groups whilst maximising power and efficiency. The main drawback concerns the complexity of design and subsequent conduct and analysis.

In summary, methods of evaluating interventions to change professional and organisational behaviour offer a range of strengths and weaknesses. Where feasible, the randomised trial is the preferred design.

1.7 The Scottish Programme for Clinical Effectiveness in Reproductive Health

The work for this thesis took place within the context of the Scottish Programme for Clinical Effectiveness in Reproductive Health (SPCERH). The Programme was launched in 1997 (74). Towards the end of the 1990's, the Scottish Executive Health Department (SEHD) reappraised the conduct and funding of national clinical effectiveness activities. CRAG activities, such as audit, had been mainly funded as fixed-term projects. The limitations of this approach in addressing national priorities and establishing stable networks had been recognised. The proposal for an integrated programme of work around reproductive healthcare was made during discussions over 1996 to 1997 between the Scottish Executive Health Department (SEHD) and representatives of key professional groups. The case for a programme was made by representatives of the Scottish branches of the Royal Colleges of Obstetricians and Gynaecologists (RCOG) and Midwives (RCM) and those leading existing national audits of reproductive healthcare. Existing activities involving clinical audit (Gynaecology Audit Project

in Scotland, GAPS) and clinical guideline development (Scottish Obstetric Guideline and Audit Project, SOGAP) in reproductive health topics had demonstrated a high degree of support and participation from professionals. However, such activities were largely being conducted in isolation from one another. SPCERH provided the opportunity to unite and coordinate these activities under the umbrella of a single programme.

1.7.1 Scope of the Programme

SPCERH was given the over-arching goal: to improve health outcomes for women and their families throughout Scotland by promoting more uniform standards of high quality, evidence-based reproductive healthcare. The Programme's work plan was based around four main roles.

Development of clinical guidelines and monitoring standards through clinical audit. Work within this role includes the administration of two standing audits on behalf of the Chief Medical Officer for Scotland: the Confidential Enquiry into Maternal Deaths; and the Scottish Stillbirth and Infant Death Survey (SSBIDS, in partnership with the Information and Statistics Division of the NHS in Scotland). SPCERH also initiates one national topic or criterion-based audit annually. To date, these audits have covered the management of pregnancy in women with Type I diabetes (141), the organisation of maternity services (142), and the prevention and management of emergencies in labour (143). One of SPCERH's precursor projects (SOGAP) was concerned with the development of four obstetric clinical guidelines. During its first year, SPCERH completed the development and dissemination of these four guidelines. The Programme emphasis later shifted from managing guideline development to nominating topics and members for SIGN guideline development groups.

Education, training and facilitation of professionals providing reproductive healthcare. In addition to disseminating reports of work and regular presentations at local units, SPCERH publishes newsletters and organises an annual Reproductive Health Forum for professionals to share and discuss experiences of approaches to improving practice.

Coordination and advice. SPCERH provides advice on other national and local audits within Scotland, as well as several projects abroad. The Programme also has a core commitment to providing professional and administrative support for Expert Advisory Groups on reproductive health topics, e.g. the provision of infertility services (144), convened as required by the SEHD.

Implementation research. Although principally an implementation Programme, SPCERH is committed to a programme of research evaluating the effectiveness of its dissemination and implementation strategies. Much of this work forms the basis of this thesis.

1.7.2 The value of clinical effectiveness programmes

At face value, programmes such as SPCERH offer a number of advantages over fixed term, stand-alone projects. The first is the opportunity to integrate and coordinate a number of related projects and build upon previous work. For example, the audit of pregnancy care in women with diabetes was based upon criteria derived from recommendations in a previously published SIGN guideline. Medium term funding is also more compatible with the time scales required for clinical audit, allowing time for completion of the 'audit cycle' rather than an isolated assessment of practice at one point in time. Hence, a re-audit of pregnancy care in women with diabetes was scheduled for five years following the first audit.

The second advantage is the opportunity for a team of professional and support staff to build up expertise and relevant networks and collaborations. This may facilitate longer term learning by the Programme based upon continuing evaluation of its activities, as well as providing training in and experience of clinical effectiveness activities for professionals temporarily employed by or seconded to SPCERH. Much collaboration between SPCERH and reproductive healthcare professionals in Scotland also depends upon mutual benefits realised and trust fostered over the longer term by a professionally led programme.

The third advantage relates to the ability of SPCERH to directly link (implementation) research to quality improvement activities. Proponents of an analogous programme in the United States suggest iterative dialogues between researchers and clinicians can enhance the relevance of research and improve the uptake of research findings (17).

Finally, reinforcement of guideline dissemination by a programme with professional credibility may enhance implementation, at least partially through the social influence of professional networks (15;145).

The value of such programmes in improving healthcare and health outcomes has not been formally evaluated. Controlled evaluations of, say, the impact of a programme compared with no programme, are probably impractical. However, it is possible to evaluate the effectiveness of strategies to improve healthcare *within the context* of a programme.

1.8 Thesis aim and objectives

This thesis aims to evaluate strategies employed by national clinical audit and effectiveness programmes in improving reproductive health care.

In order to meet this aim, this thesis will report work undertaken within a national clinical effective programme, SPCERH. This work consists of two main strands: evaluating strategies to change professional and organisational behaviour; and understanding factors that influence behaviour. The objectives are set out linked to the issues identified in this introductory chapter in Table 1.5. As this programme of work evolved over the course of a four year attachment to SPCERH, Table 1.5 also sets out approximate timings of each project.

Table 1.5. Thesis objectives.

Objective and timing	**Issues identified in introductory chapter (section)**	**Thesis chapter**
To determine which attributes of recommendations from a national audit project best explain the extent of their adoption into clinical practice *Years 1 to 2*	The potential effect modifying role of guidelines in strategies to change clinical practice (1.3.3)	2
To survey Scottish obstetricians and midwives to assess knowledge of key clinical recommendations from the Report on Confidential Enquiries into Maternal Deaths in the UK 1994-6 *Year 1*	The appropriateness of the strategy to disseminate the findings of a national audit (1.4.2) The role of a national audit as a core clinical governance activity (1.5.2) The strengths and weaknesses of an after (post-intervention) study (1.6)	3
To survey Scottish obstetricians to evaluate the impact on self-reported practice of four national clinical guidelines *Years 1 to 2*	The effectiveness of a national guideline dissemination and implementation strategy (1.4.2) The strengths and weaknesses of an uncontrolled before and after study (1.6) The value of a national clinical effectiveness programme (1.7.2)	4
To conduct a simple interrupted time series analysis to evaluate the impact of a national clinical guideline on the management of women with mild, non-proteinuric hypertension *Years 2 to 4*	The effectiveness of a national guideline dissemination and implementation strategy (1.4.2) The need for economic evaluations of implementation strategies (1.4.2) The strengths and weaknesses of a simple interrupted time series design (1.6) The value of a national clinical effectiveness programme (1.7.2)	5
To identify barriers to the implementation of a clinical guideline on women requesting induced abortion and tailor a strategy to improve care *Years 2 to 4*	Assessing the appropriateness of implementation strategies (1.4.2) Tailoring of implementation strategies according to identified needs and circumstances (1.4.2)	6
To conduct a cluster randomised trial of a strategy, delivered within a national clinical effectiveness programme, to improve implementation of a clinical guideline on women requesting induced abortion *Years 2 to 4*	The effectiveness of a guideline dissemination and implementation strategy (1.4.2) The need for economic evaluations of implementation strategies (1.4.2) The strengths and weaknesses of a cluster randomised trial design (1.6) The value of a national clinical effectiveness programme (1.7.2)	7

This programme of work involved the use of different research designs to evaluate the impact of selected initiatives to promote good practice. The choices of design were related to SPCERH's developing research agenda as well as available time and resources. Chapter 8 will provide an over-arching critique of the strengths and limitations of the study designs employed. This chapter will also draw more general lessons on the merits of various approaches to implementation relevant to a national clinical effectiveness programme. Finally, Chapter 9 will summarise lessons for SPCERH and implementation research.

Chapter 2

Attributes of clinical recommendations that influence change in practice following audit and feedback

2.1 Summary

A range of factors, or effect modifiers, can influence the effectiveness of interventions to promote adherence to clinical guidelines. Previous work indicates that attributes of clinical practice recommendations are independently associated with clinician *compliance*. This observational study assessed which attributes of clinical practice recommendations influence *changes* in clinical practice following audit and feedback.

Sixteen hospital gynaecology units in Scotland participated in a national audit project. Clinical practice recommendations covering selected gynaecological topics were developed and data collected to assess baseline (pre-intervention) compliance. Summaries of performance were fed back to consultant gynaecologists in each hospital and follow-up (post-intervention) data were collected. Compliance data were available at baseline and follow up for a total of 42 clinical practice recommendations. Altogether, 4664 case notes contributed to baseline data and 4382 to follow up data. Thirteen attributes describing clinical practice recommendations were developed, based upon previous work, and pre-tested. A panel of seven consultant gynaecologists rated the extent to which each of the 42 recommendations possessed each of the 13 attributes. Multi-level modelling was used to examine the relationship between attributes of clinical practice recommendations and compliance with the recommendations before and after audit and feedback.

Recommendations judged to be compatible with clinician values and not requiring changes to fixed routines were independently associated with greater compliance at baseline and follow-up. However, recommendations judged to be incompatible with clinician values were independently associated with greater change in practice following audit and feedback. Attributes of recommendations may influence the effectiveness of audit and feedback in secondary care.

This chapter is based upon:

Foy R, MacLennan G, Grimshaw J, Penney G, Campbell M, Grol R. Attributes of clinical recommendations that influence change in practice following audit and feedback. J Clin Epidemiol 2002; 55: 717-22.

2.2 Introduction

The implementation of valid clinical guidelines can improve the quality of health care (77). Various factors, or effect modifiers, can influence the effectiveness of interventions to promote adherence to clinical guidelines (97). Until recently, most research has focused on characteristics of clinicians or health care organisations, such as local attitudes or preparedness to change. Diffusion theory suggests that characteristics of clinical practice recommendations themselves may also influence adherence (97). Rogers described five characteristics of an innovation that could influence the diffusion process (98):

- Relative advantage – for the user(s)
- Compatibility – with personal and local norms
- Complexity
- Trialability – the extent to which an innovation can be tried temporarily and discarded if found wanting
- Observability – whether the expected results can be seen to be achieved easily.

Grilli and Lomas first assessed the association between such characteristics and compliance with clinical practice recomendations (99). They reviewed 23 published studies reporting compliance rates with 143 different recommendations developed or endorsed by official organisations. These studies covered a wide range of contexts and specialities. Insufficient data were available to assess relative advantage and complexity. Where studies provided pre- and post-recommendation data, only the latter were considered. Recommendations judged to be of high complexity were associated with lower compliance rates (mean 42%) than those judged to be of low complexity (56%). Recommendations judged to be of high trialability were associated with higher compliance rates (mean 56%) than those of low trialability (39%). No differences in compliance were found between high and low observability recommendations. However, researchers rather than the targeted clinicians made judgements about the characteristics of each recommendation. This undermines the validity of the study's conclusions as targeted clinicians may have made different judgements because of greater familiarity with the recommendations and their context.

Grol *et al* assessed the extent to which Dutch general practitioners' (GPs') compliance with recommendations from ten different national guidelines was influenced by 12 characteristics (or attributes) of the recommendations (29). A list of 16 attributes was developed following a literature review and included modified versions of the aforementioned characteristics. Forty-seven recommendations were selected from 10 different national guidelines for general

practitioners developed by the Dutch College of General Practitioners. Four researchers (including practicising GPs) independently assessed whether the attributes were present in the 47 recommendations. Three out of four researchers agreed on 87% of the ratings, whilst the remaining ratings were determined by a structured consensus meeting. Post-dissemination compliance with the guideline recommendations was assessed during a clinical audit using self-recorded data from 61 GPs. Four attributes that the researcher panel did not agree upon or were of low discriminatory value (i.e. present or not present in less than four of the recommendations) were excluded, leaving a final set of 12 attributes.

The average compliance for all recommendations was 61%. On univariate analysis, all 12 attributes were associated with compliance. On stepwise regression analysis, three attributes contributed most to explaining variance. Compliance was lower if recommendations were vaguely worded, incompatible with clinician norms and values, and disruptive to routine practice. These attributes explained 17% of the total variance.

This previous work focused on the effects of various attributes on **compliance** with recommendations, i.e. a one-off measure of performance (29;99). However, clinical guidelines are produced to promote **change** in behaviour, i.e. hereafter referring to a decrease or increase in compliance, which may be influenced by attributes different from those associated with compliance. This investigation determined whether various attributes of clinical practice recommendations influenced both compliance and change in clinical behaviour among specialists participating in a national audit programme.

2.3 Methods

Table 2.1 summarises the context and main steps of this study, now described in detail.

Table 2.1. Summary of study methods.

Context. Following a multi-centre audit of gynaecological practice across 16 hospitals in Scotland, case note data on compliance at baseline and follow-up were available for a total of 42 clinical practice recommendations
Step 1. Development and pre-testing of 13 attributes describing clinical practice recommendations
Step 2. Panel of 7 gynaecologists, using a modified RAND consensus process, rates the extent to which each of the 42 recommendations displays each of the 13 attributes
Step 3. Regression analysis to examine the influence of each attribute on compliance and change in practice with the 42 recommendations. Multi-level modelling incorporated to account for potential clustering effects of hospital data

2.3.1 Context: The Gynaecology Audit Project in Scotland (GAPS)

This study assessed change in clinical practice within the context of a national audit and feedback programme. Audit and feedback is defined as: any summary of clinical performance of health care over a specified period of time, which may include recommendations for clinical action (146). Criteria for good quality care covering selected gynaecological topics were developed and disseminated across Scotland between 1992 and 1997 (7;147-149). The criteria were developed using an approach similar to that advocated for formal clinical guideline recommendations and are hereafter referred to as 'clinical practice recommendations' (150). Their development was based upon reviews of available evidence, panel discussions, questionnaire surveys of gynaecologists and structured peer review.

Baseline compliance with the clinical practice recommendations was audited using data collected from case notes. Trained audit assistants used standardised forms to abstract data from 16 hospitals across Scotland.

Following the baseline audit period for each topic, a feedback report summarising the agreed clinical practice recommendations, the results of the audit exercise and suggestions for change in practice was circulated to all consultant gynaecologists in Scotland. Gynaecologists working in units contributing to data collection also received an individualised covering letter providing information to allow their unit to be identified and highlighting the strengths and weaknesses of the local results. The circulation of the reports was complemented by presentations of the audit results at postgraduate meetings in individual hospitals and at national meetings. Follow up data were then collected to help assess whether clinical behaviour had changed in line with the recommendations. The cycle of audit and feedback lasted approximately 18 months for each topic.

Available clinical practice data. Baseline (hereafter referred to as 'pre-intervention') and follow up ('post-intervention') data were available from case note audits for a total of 42 clinical practice recommendations relating to four topics: induced abortion, endometrial sampling, laparoscopic sterilisation and infertility. Altogether, 4664 case notes contributed to pre-intervention data and 4382 to post-intervention data. The 42 clinical practice recommendations and mean pre- and post-intervention compliance aggregated across all units are listed in Appendix 2A.

2.3.2 Step 1: Selection of attributes

Thirteen attributes of recommendations (e.g. whether the recommendation was based on sound evidence, whether it was compatible with clinician norms) were developed, based upon previous work (29;99) and modified following pre-testing on a convenience sample of four consultant gynaecologists. (See Table 2.2 for list and Table 2.3 for illustrative examples.)

2.3.3 Step 2: Rating of recommendations

A consensus panel was convened to rate the extent to which each of the 42 gynaecology recommendations displayed each of the 13 attributes. A purposive sample of seven consultant gynaecologists was recruited. Attempts were made to balance clinician age and their hospital characteristics (teaching and non-teaching; urban and rural). Seven panellists were sufficient to provide a reliable estimate of consensus and prevent 50:50 voting patterns (151).

A formal method of consensus development was required to enhance the validity of the rating process (151). Using a modified RAND process, the panel rated the extent to which each of the 42 gynaecology recommendations displayed each of the 13 attributes. All panellists were visited prior to the ratings (by RF) during which the study objectives, the meaning of the attributes, and how to rate the recommendations on a questionnaire were explained. Initially, each panellist rated the recommendations independently using an ordinal 1-9 scale. The median scores and levels of agreement from this first round of rating were fed back at a panel meeting. Structured discussion centred on the recommendation attributes over which there was maximal discordance, defined as at least three panellists scoring 1-3 *and* at least three scoring 7-9. This was necessary for 27 out of a total of 546 attribute ratings. Subsequent discussion was structured around clarification of a recommendation or attribute followed by the case to support a high or low rating of the recommendation. Much discussion concerned clarifying definitions of attributes or recommendations and the degree to which certain recommendations displayed certain attributes. Immediately after this discussion, panellists again independently rated the extent to which each

recommendation possessed each attribute. A median score of seven or more was used as the cut off point for categorising recommendations as possessing an attribute.

Clinician perceptions of the relative importance of each attribute were also explored. Following the meeting, panellists were sent a supplementary questionnaire asking them to rank the attributes in rank order (1 to 13) of what they believed would be their *overall* importance in predicting the adoption of clinical guideline recommendations.

2.3.4 Step 3: Regression analysis

Regression analyses were undertaken to assess the strength of associations between adherence to the recommendations and the extent to which each recommendation displayed each of the 13 attributes (as measured by the median panel rating). Initially the influences on compliance and behaviour change were assessed for each attribute individually (univariate analyses). Subsequently a multivariate analysis was undertaken to assess which attributes had the most significant independent effect on compliance and behaviour change.

Analyses were performed relating to (a) pre-intervention compliance, (b) post-intervention compliance and (c) change in compliance. The effect of each attribute on change in compliance is presented as an interaction term, as recommended by Cook and Campbell (130).

There was marked variation in compliance among hospitals. Multi-level regression modelling was, therefore, adopted for all analyses. Multilevel modelling is designed for the analysis of hierarchical data, and thus allowed modelling of patient outcomes whilst adjusting for the different hospital effects, e.g. hospitals might differ according to whether or not they were teaching hospitals (152). A two-level hierarchical linear model was adopted for all the analyses (patients within hospitals in this case) and a Normal error structure assumed. The multilevel regression modelling was undertaken using the statistical package MLWin. The sub-clustering of patients within clinicians was not incorporated in the model as it was assumed that clustering would be most likely at the level of the hospital, as local management protocols, if any, would be instituted at the organisational level rather than at the level of the individual clinician. In addition, the intervention feedback was aggregated at the hospital level rather than the level of the individual clinician.

The number of cases available for the assessment of compliance with each of the 42 recommendations varied widely (from 10 cases to 1510 cases). In order to avoid the possibility of spurious correlation arising from analysis based upon rate ratios (in this case percentage

compliance), the outcome variable in all regression analyses was the actual number of compliant cases, with subsequent adjustment for the total number of cases in the regression model (153).

2.4 Results

2.4.1 Panel rating of clinical recommendations

The number of clinical recommendations displaying each attribute varied widely (Table 2.2). For example, 40 (95%) of the 42 recommendations were judged to *precisely describe recommended clinical practice* and 41(98%) as *addressing a common clinical issue*. None were judged as *requiring new knowledge or skills* and only 3 (7%) each as *trialable* or as *complex*.

Table 2.2. Number (percentage) of the 42 clinical practice recommendations judged by consensus panel to possess each attribute.

Attribute	Number (%) of recommendations possessing attribute
Addresses common issue: concerned with a common clinical issue or a decision important in daily care	41 (97.6)
Precisely described: provides a sufficiently detailed and precise guide to clinical practice	40 (95.2)
Compatibility: compatible with clinicians' current norms and values in practice	32 (76.2)
Key feature: essential to the whole set of recommendations and to the ultimate goals	29 (69.1)
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses	28 (66.7)
Fits patient expectations: is likely to fit in with patient expectations	15 (35.7)
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly	8 (19.0)
Requires organisational change: requires changes in the way care is organised or additional resources	6 (14.3)
Requires changed routines: requires changes to fixed routines or habits	6 (14.3)
High profile: has a high profile in educational programmes or the media	5 (11.9)
Complex: is complex and requires many steps to do or organise	3 (7.1)
Trialable: can be tried out and discarded easily	3 (7.1)
Requires new knowledge or skills: requires the learning of new knowledge or skills	0 (0)

2.4.2 Influence of attributes on compliance

Overall mean compliance with the 42 recommendations was 58% pre-intervention and 61% post-intervention although there were marked variations in compliance among hospitals (illustrated in Table 2.3).

Many of the recommendation attributes were significantly correlated with one another (Table 2.4). The five attributes (*precisely described*, *addresses common issue*, *requires new knowledge or skills*, *complex* and *trialable*) displayed by over 90%, or under 10%, of recommendations were not included in further analysis, because of their lack of variation. Thus, only the modifying effects of eight attributes on compliance and change were studied further. When considered separately, all these eight attributes were significantly associated with compliance both before and after feedback (Table 2.5). The regression coefficients were smaller for the post-intervention compliance - primarily a reflection of the narrower range generally seen in compliance scores post-intervention. As such, there was less potential for the attributes of the recommendation to influence compliance in the post-intervention phase. The following six attributes had positive effects on compliance both pre- and post-intervention: *based upon sound evidence*; *key feature*; *compatibility*; *fits patient expectations*; *high profile*; and *observable*. Negative effects were associated with two attributes: *requires organisational change* and *requires changed routines*.

When the impact of all attributes were considered together on multivariate analysis, only two attributes were found to be significantly and independently associated with compliance at both pre- and post-intervention (Table 2.6). *Compatibility* was positively associated with compliance, i.e. the more the recommendation was compatible with clinician values the higher the compliance. *Requires changed routines* was negatively associated with compliance, i.e. the more the recommendation required changes to routines, the lower the compliance. *Compatibility* was significantly correlated with the other seven remaining attributes in the model and might represent a general marker for a range of attributes that influence practice (Table 2.4).

Table 2.3. Illustrative examples of clinical practice recommendations, compliance and ranges of compliance among hospitals.

Pre-intervention compliance and degree of behaviour change	**Recommendation**	**Mean pre-intervention compliance in hospitals (% and range)**	**Mean post-intervention compliance in hospitals (% and range)**	**Examples of attributes and clinician panel ratings**
Low compliance – low change	*Laparoscopic sterilisation:* Prior to sterilisation, women should be given an information leaflet summarising the various factors covered in the counselling	7 (0-68)	8 (0-57)	Based on sound evidence: *high* Fits patient expectations: *high* Observable: *low*
Low compliance – moderate change	*Induced abortion:* The follow up appointment should be within 14 days of the abortion	5 (0-18)	32 (0-93)	Common problem: *high* Compatible: *low* High profile: *low*
Moderate compliance – moderate change	*Management of infertility:* Drug treatments for endometriosis in women with this condition and infertility do not improve conception rates and should not be prescribed for this purpose	45 (0-100)	70 (38-100)	Based on sound evidence: *high* Fits patient expectations: *low* Observable: *low*
High compliance – no change	*Induced abortion:* The woman's rhesus status should be ascertained, and rhesus prophylaxis given following abortion, if indicated	97 (86-100)	97 (91-100)	Compatible: *high* Based on sound evidence: *high* Requires changed routines: *low*

Table 2.4. Correlation matrix for thirteen attributes.

	Compatible	Precisely described	Key feature	Common issue	Sound evidence	Changed routines	Changed organisation	Knowledge and skills	Fits patient expectation	High profile	Trialable	Observable
Complexity	-0.32**	-0.28**	-0.06	-0.08	-0.10	0.56**	0.66**	0.62**	0.15**	0.14**	-0.01	-0.04
Compatible		0.52**	0.59**	0.62**	0.36**	-0.67**	-0.55**	-0.46**	0.24**	0.46**	0.25**	0.63**
Precisely described			0.61**	0.57**	0.44**	-0.36**	-0.25**	-0.33**	0.19**	0.38**	0.13**	0.38**
Key feature				0.38**	0.75**	-0.48**	-0.40**	-0.11*	0.20**	0.60**	0.18**	0.41**
Common issue					0.38**	-0.37**	-0.14**	-0.26**	0.24**	0.40**	0.15**	0.36**
Sound evidence						-0.38**	-0.29**	-0.05**	0.07	0.51**	0.24**	0.26**
Changed routines							0.71**	0.48**	-0.02	-0.37**	-0.05	-0.39**
Changed organisation								0.46**	0.03	-0.16**	-0.21**	-0.19**
Knowledge and skills									0.02	0.01**	-0.09	-0.27**
Fits patient expectation										0.25	0.15**	0.26**
High profile											0.21**	0.41**
Trialable												0.26**

** $p < 0.01$, *$p < 0.05$

Table 2.5. Univariate analyses of the association between eight attributes and compliance with recommendations.

Attribute	Regression coefficient (95% CIs)		
	Pre-intervention compliance	Post-intervention compliance	Change pre- to post-intervention [a]
Compatible	8.94 (7.42, 10.46)	5.79 (4.43, 7.14)	-3.34 (-5.37, -1.31)
Key feature	6.97 (5.27, 8.66)	4.96 (3.48, 6.44)	-2.32 (-4.56, -0.08)
Based upon sound evidence	3.91 (1.84, 5.98)	3.75 (2.00, 5.50)	-0.30 (-3.00, 2.40)
Fits patient expectations	3.00 (1.07, 4.93)	1.93 (0.03, 3.57)	0.72(-1.79, 3.23)
Observable	5.06 (3.59,6.53)	3.42 (2.15, 4.69)	-1.68 (-3.62, 0.26)
Requires organisational change	-5.63 (-6.99, -4.27)	-3.66 (-4.84, -2.47)	2.19 (0.39, 3.99)
Requires changed routines	-6.04 (-7.26, -4.82)	-4.00 (-5.07, -2.93)	2.18 (0.56, 3.80)
High profile	4.84 (2.14, 7.54)	4.29 (2.41, 6.17)	-0.63 (-2.12, 3.38)

[a] Coefficient of interaction term

Table 2.6. Results of multivariate regression analysis of the association between the attributes and compliance with recommendations.

Variable	Regression coefficient (95% CI)	Significance of regression
Pre-intervention compliance		
Compatible	6.76 (4.73, 8.88)	<0.001
Requires changed routines	-2.52 (-4.10, -0.95)	
Post-intervention compliance		
Compatible	4.26 (2.44, 6.08)	<0.001
Required changed routines	- 1.77 (-3.19, -0.35)	
Change in compliance pre- to post-intervention		
Compatible	-3.34 (-5.37, -1.31) [a]	<0.001

[a] Coefficient of interaction term

2.4.3 Influence of attributes on behaviour change

Considered separately, four attributes were significantly associated with **behaviour change**. However, the directions of these associations were reversed in comparison with those obtained for **compliance**. The attributes positively associated with compliance (*compatibility* and *key feature*) were negatively associated with behaviour change, and those negatively associated with compliance (*requires organisational change* and *requires changed routines*) were positively associated with behaviour change (Table 2.5).

When the impact of all attributes were considered together on multivariate analysis, only *compatibility* was found to be significantly and independently associated with change in compliance (Table 2.6). The more compatible the recommendation with clinician norms and values the smaller the behaviour change pre- to post-intervention.

2.4.4 Panel perceptions of attributes

All 7 panellists responded to the supplementary questionnaire asking them to rank the attributes in order (1 to 13) of what they believed would be their *overall* importance in predicting the adoption of clinical guideline recommendations. The panel judged that clinical behaviour would be best predicted by recommendations *based upon sound evidence* (Table 2.7).

Table 2.7. Panellists' ranking of the overall importance of each of the 13 attributes in predicting adoption of recommendations (1 = most important).

Attribute	Panellists' ranking in predicting adoption of recommendations
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses	1
Precisely described: provides a sufficiently detailed and precise guide to clinical practice	2
Addresses common issue: concerned with a common clinical issue or a decision important in daily care	3
Compatibility: compatible with clinicians' current norms and values in practice	4
Key feature: essential to the whole set of recommendations and to the ultimate goals	5
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly	6
Requires organisational change: requires changes in the way care is organised or additional resources	7
Requires changed routines: requires changes to fixed routines or habits	8
Complex: is complex and requires many steps to do or organise	=9
Requires new knowledge or skills: requires the learning of new knowledge or skills	=9
High profile: has a high profile in educational programmes or the media	11
Trialable: can be tried out and discarded easily	12
Fits patient expectations: is likely to fit in with patient expectations	13

2.5 Discussion

2.5.1 Principal findings

Certain attributes of clinical practice recommendations were associated with variations in compliance and behaviour change before and after an audit and feedback programme in secondary care. Consistent with previous work (29), recommendations compatible with clinician norms and values and not requiring changed routines were independently associated with higher compliance. However, clinical practice recommendations are intended to change behaviour, and a different picture emerged when changes in compliance following audit and feedback were examined.

Recommendations less compatible with clinician norms and values were associated with greater improvements in clinical practice, probably because of a greater potential for change due to low baseline compliance. Those recommendations more compatible with clinician norms and values

thus may have been associated with potential ceiling effects, with limited scope for further improvements in practice. Nevertheless, the multi-level model included an interaction term which accounted for temporal changes (130). Therefore, the association between lower compatibility and changes in practice cannot solely be attributed to greater scope for improvement in the pre-intervention phase.

2.5.2 Strengths and weaknesses of the study

This is the first study to investigate whether attributes of recommendations independently influence **change** in clinical behaviour as opposed to **compliance**. Much implementation research is still based upon a 'black box' approach but it is important to explore the potential impact of a range of effect modifiers (such as attributes of clinical practice recommendations) to improve understanding of why interventions may or may not succeed in changing professional behaviour.

Objective data from case notes were used to measure compliance in contrast to previous studies which relied partially or completely on self-reports (29;99). Self-reports were associated with higher levels of compliance in the study by Grilli and Lomas, suggesting observation bias (99). Case notes may not contain all relevant information to assess whether recommendations are followed in clinical practice. Although several clinical practice recommendations were concerned with adequate recording of actions in the case notes, it is possible that the use of such data might underestimate actual adherence to some recommendations. However, assuming such a bias applies equally to the pre- and post-intervention data, it is unlikely to under-estimate changes in behaviour.

A rigorous consensus process was used to assess the attributes of clinical practice recommendations based upon the perceptions of the targeted clinicians. Structured processes are associated with greater validity than informal methods (151). Given the retrospective nature of this study, it is possible that panel ratings were biased by the gynaecologists' knowledge of how widely certain recommendations were actually adopted into practice. However, given the large variations in practice for many recommendations and the fact that current levels of compliance were not explicitly raised during the panel meeting, this seems unlikely to be a major source of bias. Furthermore, the attribute which clinicians predicted would have the greatest ability to explain variation, *based on sound scientific evidence*, did not have a significant independent effect.

The use of multi-level modelling, incorporating individual hospital effects, was justified given the marked variation in practice observed among different hospitals. Analyses based on patient

level data, which did not account for 'clustering' effects, might have over-emphasised the significance of any results (152).

The explanatory power of certain attributes may have been reduced if panel members tended to rate recommendation attributes according to their own pre-conceived ideas about the relative importance of each attribute in influencing practice rather than the extent to each recommendation displayed each attribute. Therefore, it is possible that *trialability* did not appear to have any influence on practice, in contrast to earlier work (99) because of the panel members' low expectations that such a factor might influence their own practice. However, in the study by Grilli and Lomas, recommendation attributes were rated by researchers rather than by guideline target users.

Grol et al found that *precisely described* recommendations were associated with higher compliance (29). In this study, the precision of clinical practice recommendations explained no variation because the vast majority of recommendations were rated as *precisely described*, thus reducing this attribute's explanatory power. Further evidence for the overall importance of precision comes from a randomised comparison of the effect of non-specific versus specific guideline recommendations which demonstrated that the latter improved clinical decision-making (154).

Two attributes, *compatibility* and *requires changed routines*, were associated with significant and independent effects on compliance in both this and the primary care study (29). This finding strengthens the likelihood that these two attributes have more generalisable influences on compliance with recommendations within the context of national clinical audit projects. However, in the stepwise regression analysis, *compatibility* was significantly correlated with a number of other attributes. *Compatibility* might then operate as a general marker for other attributes which influence practice.

2.5.3 Possible mechanisms and implications

Audit and feedback is variably effective as a strategy to improve professional practice (155); this may be related to factors such as the method of feeding back performance data to clinicians, the actual content of the recommendations, or the wider context.

In this study, audit and feedback appeared to be effective in promoting the implementation of recommendations judged to be less *compatible with clinician norms and values*. For example, in the care of women undergoing induced abortion, pre-intervention compliance was low (5%) for one such recommendation, 'The follow-up appointment should be within 14 days of the

abortion.' Following audit and feedback, compliance increased six-fold by 27% (to 32%). Feedback permitting comparisons among hospitals during the audit programme may therefore have prompted action on recommendations previously regarded as too disruptive or incompatible to implement. In contrast, pre-intervention compliance was high (97%) for a recommendation rated as *compatible with clinician norms and values*, 'The woman's rhesus status should be ascertained, and rhesus prophylaxis given following abortion, if indicated'. Subsequently, there was little scope for improvement in compliance with this recommendation following audit and feedback.

Different attributes may have influenced change in clinical behaviour following an intervention other than audit and feedback (e.g. interactive educational programmes). For example, experience in the dissemination of four clinical guidelines within the context of a national clinical effectiveness programme suggests that adherence to one guideline (albeit clinician reported) did not improve because of the relatively complex nature of its recommendations (156) (Chapter 4).

One systematic review suggests that implementation strategies based upon a 'diagnostic analysis' – identification of potential needs and barriers – are more likely to be effective (157). Attributes of individual recommendations appear to influence both compliance and behaviour change and need to be considered when planning implementation activities. It is likely that the effects of different implementation strategies may be modified by the attributes of recommendations. At present there is only limited information about how such attributes modify the effects of implementation strategies. As further evidence becomes available consideration of the attributes of practice recommendations may assist in the choice of implementation strategy.

2.5.4 Unanswered questions and future research

Further research is required to determine how attributes of recommendations modify the effectiveness of different interventions in different contexts. These studies should focus on behaviour change rather than compliance and use the most robust estimates of behaviour change, preferably from randomised trials.

2.6 Conclusion

This observational study assessed which attributes of clinical practice recommendations influence changes in clinical practice following audit and feedback. Recommendations judged to be compatible with clinician values and not requiring changes to fixed routines were independently associated with greater compliance at baseline and follow-up. However, recommendations judged to be incompatible with clinician values were independently associated

with greater change in practice following audit and feedback. Attributes of recommendations may influence the effectiveness of audit and feedback in secondary care.

Chapter 3

Survey of professionals' knowledge of key recommendatons from a national confidential enquiry report

3.1 Summary

The Confidential Enquiries into Maternal Deaths aim to assess the main causes of maternal deaths, identify substandard care and promulgate findings to all relevant health professionals. Following publication of previous Reports, the organisation of maternity services has improved but the impact on individual clinical staff is unknown.

Scottish obstetricians and midwives were surveyed by telephone interviews to assess knowledge of key clinical recommendations from the Report on Confidential Enquiries into Maternal Deaths in the UK 1994-6. The main outcomes were awareness of key recommendations from the Report and participation in implementation activities. 201 out of 208 staff (97%) agreed to participate. Two-thirds (131; 65%) stated they had read at least some of the Report. A median of 3 out of 18 key recommendations were recalled, with recall of newer issues being lower. Although reported access to key clinical guidelines was high, other dissemination and implementation activities were used inconsistently, if at all.

Publication of future Confidential Enquiry Reports should be accompanied by active dissemination strategies, possibly emphasising newer or more important recommendations.

This chapter is based upon:

Foy R, Nelson F, Penney GC. Awareness of key recommendations from the Report on Confidential Enquiries into Maternal Deaths 1994-6 among obstetric and midwifery staff in Scotland. Journal of Clinical Excellence 2000;2:27-32.

3.2 Introduction

3.2.1 The Confidential Enquiries into Maternal Deaths

The Confidential Enquiries into Maternal Deaths (CEMD) aim to draw generalisable lessons for maternity care by scrutinising events preceding maternal deaths in the United Kingdom. Participation in the Enquiries and implementation of subsequent recommendations represent core functions within clinical governance (158). Many maternal deaths are associated with episodes of sub-standard care. Furthermore, instances of sub-standard care related to mortality may represent only the 'tip of the iceberg', with a large proportion of 'near miss' events likely. Although maternal mortality has continued to fall, similar errors in clinical care tend to recur. The implementation of the Reports' recommendations therefore continue to represent a major challenge for maternity services, especially in light of the professional time and interest invested in the conduct of the Enquiries and production of the Reports.

The 1994-6 Report, *Why Mothers Die*, additionally highlighted wider public health issues derived from a more detailed assessment of deaths from domestic violence, car accidents and those occurring as a result of psychiatric illness or substance abuse (159). The Report was also marked by a change in style and emphasis, intended to make it more readable and have a greater impact in improving care.

In general, the main causes of substandard care were attributed to:

- Failures of some junior medical, obstetric staff or accident and emergency (A&E) staff, GPs, and midwives to diagnose or refer cases;
- Failure of consultants to attend in emergencies or to delegate appropriately;
- Inappropriate treatment;
- In some units, lack of protocols for the treatment or prevention of conditions such as massive haemorrhage or pulmonary embolism; and
- Lack of team work.

The Report made a number of general recommendations, including the provision of guidelines for key problems and the implementation of such guidelines subject to regular audit. Units were also encouraged to organise regular "fire drills" for cases of massive haemorrhage so that all members of staff became familiar with required action, such as the delivery of large quantities of cross-matched blood to labour wards without delay.

Specific recommendations were made regarding the recognition and management of obstetric complications, such as ectopic pregnancy, pulmonary embolism and pre-eclampsia. The need for close monitoring of medical conditions during pregnancy was emphasized. For example, for women with epilepsy, it is important that staff check with relatives that they know what to do in the case of a fit and provide instruction on how to place the patient in a recovery position once the fit is over.

The Report identified the need for staff training in the recognition and management of domestic violence, the early identification and management of postnatal depression and the correct use of seatbelts. For example, antenatal care provides an important opportunity to detect domestic violence. Estimates of the prevalence of domestic violence within the current pregnancy among women attending antenatal care vary, with ranges of 4 to 17% reported in the US (160). Domestic violence is associated with poorer outcomes, including increased rates of miscarriage, preterm birth, fetal injury and fetal death (161). Clinical practice recommendations highlight the importance of enquiring about domestic violence as a routine component of antenatal care (162)

3.2.2 Dissemination of the Reports

Copies of the Report were sent to all consultant obstetricians and heads of midwifery in Scotland. Given the multidisciplinary nature of maternity care, it is important that key clinical recommendations are disseminated widely. The 1994-6 Report was supplemented by an executive summary, listing key recommendations, intended for wider distribution among all staff involved in maternity care.

An audit of all UK consultant-led maternity units in 1997 suggested that the vast majority had made organisational changes in response to previous Reports (163). Compared with a previous audit (164), more units had introduced clinical guidelines for the management of major haemorrhage and eclampsia.

However, it is uncertain as to whether antenatal and labour ward staff knew of or had access to guidelines or how aware they were of key recommendations from the Reports. Effective dissemination represents a critical first step in implementation. This study therefore set out to assess awareness of key recommendations from the 1994-6 Report among obstetricians and midwives in Scotland and their participation in local dissemination activities.

3.3 Methods

3.3.1 Development of interview schedule

An interview schedule for a telephone survey was developed to include: awareness of key recommendations from the report and main causes of maternal mortality; reported clinical practice; access to clinical guidelines highlighted by the Report; and participation in educational activities relevant to the Report. Eighteen key recommendations were identified from the summary Report. The interview schedule was piloted on a sample of doctors and midwives at one hospital and modified (Appendix 3A).

3.3.2 Sampling frame

The sample consisted of obstetric (senior house officer, specialist registrar and consultant) and midwifery (midwives in charge of labour wards and antenatal clinics) staff from all 23 consultant-led maternity units in Scotland. Prior permission to undertake the survey was obtained from all clinical directors and heads of midwifery. A letter also went out to all clinical staff forewarning them of the survey which would assess 'aspects of maternity care'. The precise nature of the survey was not stated in advance to prevent staff from making special efforts to consult the 1994-6 Report in advance.

The samples comprised medical and midwifery staff on duty on the day each hospital was called. Midwives in charge of labour ward were asked to provide the names of medical staff providing obstetric cover on the day they were telephoned. Medical staff were then telephoned and given the choice of being interviewed that day or at a more convenient time later.

Most units were sampled twice with five staff members being approached on each occasion. In the three smallest units, only three staff members were approached. In one larger unit, only four staff members were eligible on the second occasion. Thus, 208 staff were approached for interview.

3.3.3 Administration of interviews

The interviews took place 6 months after the Report was published. The precise topic of the survey was only revealed at the time of interview. The confidential nature of this survey and the fact that it was to assess dissemination of the Report rather than individual competence were explained to all potential participants.

Enquiry was made into recall of key recommendations with minimal prompting by the interviewers. The pilot suggested that interviewees would be unable to provide a comprehensive

list of key recommendations. In order to provide a target to encourage responses, interviewees in the definitive survey were asked if they could recall three *or more* key recommendations from the Report.

Midwives were asked what aspects of social history, including domestic violence, they made enquiry into at booking clinics. Obstetricians were asked whether they routinely covered the same details when taking a history or checked midwives' booking notes for this information.

3.3.4 Analysis

In recall of key recommendations, respondents was rated as scoring a 'direct hit' if they recalled all aspects of a recommendation or a 'near miss' if they could only recall one aspect. For this analysis, mention of at least one aspect of a recommendation was counted as a positive response.

Data were entered into an Access database (165) and analysed using the Statistical Package for Social Sciences (SPSS) version 8 (166). Median recall scores were compared using the Mann-Whitney test with 2-sided P values.

3.4 Results

3.4.1 Response rate

Two hundred and one out of 208 staff agreed to be interviewed (response rate 97%). Three refused to be interviewed and four could not be contacted after at least 6 attempts. Respondents were evenly distributed by grade and discipline according to the sampling frame.

3.4.2 Awareness of Report

One hundred and eighty-five (92%) were aware of the 1994-6 Report (Table 3.1) and 131 (65%) reported having read at least some of the Full Report or Executive Summary. Fewer had participated in educational meetings or tests of emergency protocols ('fire drills'). Reported access to clinical guidelines was high except for the management of women who declined blood products and the management of ectopic pregnancy. The latter were mentioned as being more frequently located in gynaecological units.

Table 3.1. Reported participation in or access to dissemination activities.

Recognition, receipt and reading	*Number (%)*
Awareness of Report	185 (92)
Received or seen copy of Full Report	119 (59)
Received or seen copy of Executive Summary	79 (39)
Read at least some of Full Report	104 (52)
Read at least some of Executive Summary	67 (33)
Training activities	
Lecture specifically on the most recent Report (didactic style)	19 (10)
Group tutorial specifically on the most recent Report (interactive style)	40 (20)
Tests of emergency obstetric protocols ('fire drills') in preceding 6 mths	49 (25)
Access to local guidelines or policies	
Management of pre-eclampsia and eclampsia	195 (97)
Management of obstetric haemorrhage	186 (93)
Use of thromboprophylaxis	179 (89)
Antibiotic cover for caesarean sections	169 (84)
Management of women who decline blood products	102 (51)
Investigation and management of ectopic pregnancy	106 (53)

3.4.3 Recall of key recommendations

Respondents each recalled a median of three out of 18 key recommendations (range 0 to 10). At least a third of responders recalled issues relating to the management of eclampsia and pre-eclampsia, protocols for emergencies, consultant attendance and delegation, and prophylaxis against thromboembolism (Table 3.2). However, recall of certain preventive issues such as seatbelt use, domestic violence, antibiotic prophylaxis in caesarean section and awareness of puerperal sepsis was much lower. Forty-seven respondents (23%) were unable to recall any recommendations.

Table 3.2. Recall of key recommendations from the Report.

Key recommendations	Number (%) of respondents
Recognition of main direct causes of death	53 (26)
Importance of prompt diagnosis or referral of suspected serious disease	49 (24)
Identification of women at risk of postnatal mental illness or self harm during antenatal care	15 (7)
Enquiry about domestic violence	8 (4)
Education of women about the use of seatbelts	4 (2)
Education of women about symptoms associated with pre-eclampsia	11 (6)
Education of women about first aid of epileptic fits	12 (6)
Early attention to chest or leg symptoms to exclude presence of thromboembolism	62 (31)
Management of eclampsia or pre-eclampsia by a single senior clinician	88 (44)
Pregnancy testing considered in any woman with unexplained abdominal pain	11 (6)
Prompt management of suspected ectopic pregnancy	33 (16)
Assessment of risk factors in considering prophylaxis against thromboembolism in all women undergoing caesarean section	66 (33)
Use of prophylactic antibiotics in caesarean section	9 (5)
Awareness of puerperal sepsis	6 (3)
Participation in confidential enquiries	6 (3)
Consultant attendance or appropriate delegation in emergencies	77 (38)
Need for units to have protocols for massive haemorrhage or pulmonary embolism	88 (44)
Unit "fire drills" for emergencies	7 (4)

3.4.4 Awareness of causes of maternal mortality

Asked about direct causes of maternal mortality, most respondents ranked thromboembolism and pregnancy induced hypertension within the top three but omitted amniotic fluid embolism (Table 3.3). Respondents were less aware that epilepsy and psychiatric illness represented major indirect causes of maternal death. In response to a separate question about epilepsy, 120 out of 163 staff involved in antenatal care (74%) could recall neither of the specific recommendations pertaining to personal safety (not bathing unsupervised and that friends or relatives know what to do in the event of a fit).

Table 3.3. Knowledge of main causes of direct and indirect maternal deaths.

Direct causes (in order of actual frequency)	Number (%) ranked amongst top 3 causes
Thromboembolism	160 (80)
Pregnancy induced hypertension	173 (86)
Amniotic fluid embolus	19 (9)
Early pregnancy problems (e.g. ectopic)	11 (5)
Sepsis (or infection)	26 (13)
Haemorrhage	150 (75)
Uterine rupture	3 (1)
Fatty liver of pregnancy	1 (0)
Anaesthesia	16 (8)
Indirect causes	
Cardiac disease	143 (71)
Epilepsy	48 (24)
Psychiatric illness (including suicide)	20 (10)

3.4.5 Social history taking

Enquiry about domestic violence was made least frequently of any aspect of social history taking (Table 3.4). Out of 160 staff who provided antenatal care, 18 (11%) reported 'usually' enquiring about domestic violence whilst a further 52 (32%) enquired if 'indicated' (Table 4). Out of 40 midwives working in antenatal clinics, 6 (15%) routinely enquired whilst 18 (45%) did so 'if indicated'.

Table 3.4. Number of respondents (%) personally enquiring about or discussing issues during antenatal care.

Enquiry made at antenatal booking	Obstetricians (n=120)		Clinic midwives (n=40)	
	'Usually'	'If indicated'	'Usually'	'If indicated'
Previous psychiatric disorders	49 (41)	48 (40)	34 (85)	5 (13)
Episodes of self-harm	14 (12)	53 (44)	7 (18)	24 (60)
Domestic violence	12 (10)	32 (27)	6 (15)	18 (45)
Substance abuse	71 (59)	34 (28)	31 (78)	8 (20)
Alcohol intake	87 (72)	21 (18)	37 (92)	3 (8)

3.4.6 Associations between participation in dissemination activities and recall of key recommendations

Respondents who reported having read at least some of either report recalled a median of 3 recommendations compared with 0.5 for those who had not ($Z=6.73$, $2p<0.001$). Respondents who had attended any educational meeting recalled a median of 4 recommendations versus 2 for those who had not ($Z=4.59$, $2p<0.001$).

3.5 Discussion

3.5.1 Main findings

Overall awareness of the content of Report was low, especially of those recommendations included for the first time in the current report. Although most staff reported access to major clinical guidelines, other educational efforts to disseminate key CEMD recommendations were used inconsistently, if at all.

3.5.2 Strengths and weaknesses of design

The high response rate and quasi-random method of selecting participants improve the likelihood that the sample was representative of obstetricians and senior midwives in Scotland. Attempts were also made to minimise biases which might over-estimate awareness of the Report's content. It is likely that the pressure of participating in telephone interviews led to an under-estimate of respondents' actual knowledge. However, responses to a postal questionnaire might have over-estimated awareness of recommendations (because some respondents might have been prompted to read the Report as they answered questions). Furthermore, information on the relative levels of recall and recognition of recommendations indicates which recommendations appeared less important to clinical staff or require reinforcement in future dissemination activities.

Participants recalled a median of three key recommendations, albeit often only in part. This median may have been influenced by framing of the question (as discussed in 3.3.3) although participants were encouraged to list more recommendations.

This study was not designed to assess the effectiveness of national or local dissemination activities. Confounding may explain much of the apparent association between higher recall of recommendations and reading of the reports or attendance at educational meetings. For example, staff who received or read the reports may already have been more interested in the issues it raised and so recalled more recommendations.

3.5.3 Policy implications

Knowledge of newer issues (e.g. the contribution of amniotic fluid embolism) appeared low compared with those mentioned in previous reports (e.g. consultant attendance). The Report incorporated a revised method for diagnosing deaths from amniotic fluid embolism (whereby the clinical picture alone may fulfil diagnostic criteria without pathological evidence). It is possible that the perceived contribution of postpartum haemorrhage to maternal deaths was raised following the recent dissemination of a guideline on this topic in Scotland (167).

The Report's public health messages appear to have been poorly assimilated, particularly those pertaining to the correct use of seatbelts and domestic violence. Such recommendations may have been given lower priority or seen as more problematic to implement.

There is clearly much scope for improvement, especially as self-reporting may over-estimate actual practice (37;129). These findings have implications for staff training and access to support for women. Several midwifery respondents mentioned that they were currently exploring acceptable ways to identify victims of domestic violence. Midwives frequently mentioned difficulties either adopting an appropriate form of words to enquire about domestic violence or being able to interview women in the absence of their partners. Brief screening questionnaires appear to be more sensitive at detecting abuse than less structured enquiry (168). Appropriate support is necessary following detection. A previous survey asked representatives of the same maternity units what contact details for access to support agencies were given to women (169). Women's Aid or another source of support for victims of domestic violence were spontaneously mentioned in only four units.

The simple distribution of printed educational material is relatively ineffective at improving clinical practice (170). An analysis of trends in perinatal mortality found no evidence to support the effectiveness of a related activity, locally-based enquiries into perinatal death (171). The re-audit of the implementation of the 1991-3 Report found improvements in the organisation of maternity services and guideline availability (163). It is of concern that awareness of key recommendations was so low, especially given the high profile of the Confidential Enquiry into Maternal Deaths. Newer recommendations, such as enquiry about domestic violence, may require greater emphasis in future reports and additional support to implement at a local level.

3.5.4 Unanswered questions and future research

Future work should address how the format of the Report can highlight key recommendations more effectively and test the impact of additional interventions to support their implementation.

3.6 Conclusion

Participation in the Confidential Enquiries represents a core clinical governance task. However, the time and effort expended in producing the Reports need to be matched by appropriate dissemination activities. Among obstetric and midwifery staff in Scotland, knowledge of key recommendations from the last Report (1994-6) was poor. Educational efforts to disseminate recommendations were used inconsistently, if at all, at a local level. Publication of future Reports should be accompanied by active dissemination and implementation strategies.

Chapter 4

Before-and-after survey of professionals' knowledge of and reported adherence to national clinical guidelines

4.1 Summary

Scottish obstetricians were surveyed to evaluate the impact of four Scottish Obstetric Guidelines and Audit Project guidelines on self-reported practice. The guidelines comprised: *The Preparation of the Fetus for Preterm Delivery, The Management of Mild, Non-proteinuric Hypertension in Pregnancy, The Management of Pregnancy in Women with Epilepsy* and *The Management of Postpartum Haemorrhage*. The guidelines were disseminated by means of a national meeting attended by medical and midwifery representatives from all Scottish maternity units and by postal circulation to relevant medical and midwifery staff. Publication and dissemination were undertaken under the auspices of the SPCERH.

Questionnaire surveys were administered before and after dissemination of the guidelines to 161 consultants and senior specialist registrars in Scotland. The response rates to the baseline and follow-up surveys were 85% and 74% respectively. Over 90% of the responding obstetricians kept the guidelines for reference and 85% had been prompted to change or reconsider their practice. Reported compliance improved significantly for recommendations covering: the use of tocolysis in women at risk of pre-term labour; the use of prophylactic antibiotics or entry to a clinical trial for pre-term, pre-labour rupture of the membranes; the initiation of steroid therapy in women with insulin-dependent diabetes mellitus; and the prescribing of periconceptual folic acid and vitamin K to women with epilepsy. There were no significant improvements in relation to mild, non-proteinuric hypertension or post-partum haemorrhage.

There were significant improvements in the reported management of women at risk of preterm labour and those with epilepsy. However, reported practice in relation to mild, non-proteinuric hypertension improved little. The guideline recommendations for this topic were relatively complex and established patterns of practice perhaps more resistant to change. For the management of postpartum haemorrhage, knowledge of relevant recommendations from the 1991-3 Report on the Confidential Enquiry into Maternal Deaths did not improve, partly because baseline knowledge was already high for the majority of the recommendations.

This chapter is based upon:

Foy R, Penney G, Greer I. The impact of national clinical guidelines on obstetricians in Scotland. Health Bulletin 2001;59:364-372.

4.2 Introduction

4.2.1 Clinical guidelines and clinical audit

Clinical guidelines and clinical audit represent two fundamental components of the NHS clinical effectiveness (172) and clinical governance (158) initiatives (Chapter 1). These initiatives represent national efforts to promote more uniform standards of high quality, evidence-based care. Within these recent, quality-promoting initiatives, attempts have been made to bring together guideline, audit and related activities in a more concerted fashion. Previously, audit (173) and guidelines (174) had been promoted as separate activities and were often undertaken in isolation. (70)

4.2.2 The Scottish Obstetric Guideline and Audit Project (SOGAP)

SOGAP was a guideline development project initiated by the Scottish Executive Committee of the Royal College of Obstetricians and Gynaecologists (RCOG) and funded by the Clinical Resource and Audit Group (CRAG). Between 1995 and 1997, four obstetric guidelines were developed in response to demand and concerns mainly raised by clinicians:

The Preparation of the Fetus for Preterm Delivery. Preterm delivery occurs in around 7% of all pregnancies and is a major cause of infant mortality and morbidity (175). In Scotland in 1995, there were 3228 singleton livebirths at gestations of under 37 weeks, of whom 111 (3.4%) died in the neonatal period. Rigorous evidence exists that appropriate management (principally administration of corticosteroids) prior to anticipated preterm delivery results in a large in neonatal deaths due to respiratory distress syndrome, intraventricular haemorrhage and necrotising enterocolitis. However, a Scottish audit over 1990-3 indicated that only 29% of infants delivered before 31 weeks received a full course of steroids prior to delivery (176).

The Management of Mild, Non-proteinuric Hypertension in Pregnancy. Hypertensive disorders of pregnancy comprise one of the major causes of maternal death in the UK and are associated with increased risks of stillbirth and neonatal death (48). The reports of the Confidential Enquiry into Maternal Deaths (CEMD) repeatedly highlight the need for clear guidelines for the management of severe hypertensive disorders and suitable protocols should already be in place in Scottish maternity units (159;177). Less attention had been paid to the management of mild, non-proteinuric hypertension in pregnancy. There was confusion about the relationships between various categories of mild disease and about their potential to progress to severe disease.

The Management of Pregnancy in Women with Epilepsy. Epilepsy affects around 1 in 200 women attending antenatal clinics (178). Epilepsy is associated with an increased risk of

congenital malformations, further raised if the mother is taking anti-epileptic drugs. The babies of women born with epilepsy are at increased risk of neonatal problems, including haemorrhagic disease of the newborn. For the mother, pregnancy may affect the progress of epilepsy, with seizure frequency increasing by a third. An earlier survey of Scottish obstetricians had indicated that one fifth were dissatisfied with the level of care then received by their patients with epilepsy and that the majority considered guidelines necessary (179).

The Management of Postpartum Haemorrhage. Obstetric haemorrhage remains one of the major causes of maternal death (167). The CEMD Reports revealed no consistent fall in deaths related to haemorrhage, the majority of which were judged to involve substandard care (177). An audit of compliance with recommendations made in previous CEMD Reports revealed a number of problems and deficiencies relating to obstetric units in Scotland (164). Only 62% of obstetric units in Scotland reported having a protocol for the management of massive haemorrhage.

The guidelines were developed according to a methodology developed by the Scottish Intercollegiate Guidelines Network (SIGN) (180;181). Guideline development groups comprised a range of professionals involved in the provision of care around each guideline topic and relevant patient representatives. Relevant literature was identified via searches of Medline, the Cochrane Library and secondary references, supplemented by material known to group members. Individual recommendations within the guidelines were graded under the scheme then used by SIGN (181):

- Grade A: requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation;
- Grade B: requires availability of well-conducted clinical studies but no randomised clinical trials on the topic of the recommendation;
- Grade C: requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities.

Advanced drafts of the guideline were peer reviewed and amended prior to submission to the SIGN editorial board and the Scottish Executive Committee of the RCOG.

4.2.3 Dissemination strategy

The guidelines were disseminated by means of a national meeting attended by medical and midwifery representatives from all Scottish maternity units and by postal circulation to relevant medical and midwifery staff. Publication and dissemination were undertaken under the auspices of SPCERH.

In the spirit of an integrated clinical effectiveness programme, the development and dissemination of these four guidelines was complemented by an audit exercise which aimed to assess obstetricians' baseline compliance with the guideline recommendations and to assess any changes in practice subsequent to dissemination. The findings of this survey of self-reported practice are described here.

4.3 Methods

4.3.1 Questionnaire development

A questionnaire enquiring into aspects of practice related to each of the guidelines was developed. This included a mix of direct questions about adoption of recommendations, a choice of responses to vignettes related to recommendations and (for postpartum haemorrhage only) a series of true/false questions. In addition to general questions about whether the guidelines had been kept and influenced practice, the questionnaire also enquired into receipt, local adoption and local clinical audit of the guidelines.

4.3.2 Sampling frame and administration of questionnaire

The questionnaire was posted to 161 senior obstetricians in 1997, comprising all consultants and all identifiable senior registrar/ year 4 and 5 specialist registrars in Scotland. The findings of the baseline audit questionnaire were disseminated at the time of distribution of the guidelines. A shorter questionnaire was posted to the same obstetricians two years later, containing a subset of the original questions which mainly addressed those recommendations where there was some potential for change in clinical practice (Appendix 4A). All initial non-responders to both questionnaires received one reminder.

4.3.3 Analysis

Responses were entered into an Access database (165) and analysed using SPSS (166). Responses were categorised as 'appropriate' if they were consistent with recommendations in the guidelines and included in the analysis only when matched questions from both the baseline and follow-up questionnaires had been answered. The exact matched pairs test was performed using Arcus (182;183) and 2-sided P values were used. To allow simpler presentation of results, the overall proportion and direction of change in practice is presented in addition to baseline compliance. As this way of presenting results could mask substantial shifts in opinion from compliant to non-compliant responses, larger shifts (20% or more of respondents) in this direction are highlighted in the text. One way analysis of variance (ANOVA) was used in the comparison of multiple means.

4.4 Results

4.4.1 Response rates

During the period between the two surveys, 19 of the original 161 obstetricians retired from obstetric practice or moved outwith Scotland. Of the 142 obstetricians available for survey at both time points, 121 (85%) returned the baseline questionnaire and 105 (74%) the follow-up questionnaire. Ninety-two of these 142 obstetricians (65%) completed *both* questionnaires and results are subsequently based upon this group.

4.4.2 Reported receipt and use of the guidelines

Eighty-four (91%) obstetricians reported that they had kept the guidelines for future reference whilst the others were uncertain of their location or had thrown them away. Seventy-eight (85%) reported that they had changed or reconsidered aspects of their practice in response to any of the guidelines. Of these, 30 (33%) found the guidelines sufficiently relevant to prompt changes in some aspects of practice, whilst 48 (52%) were prompted to reconsider their practice. The remainder found them of general interest (12, 13%) or of no real interest (1, 1%). Approximately half of all respondents reported local adoption of the guidelines but fewer reported their use in clinical audit (Table 4.1). Of the four guidelines, that on mild, non-proteinuric hypertension was least often adopted or used for audit locally.

Table 4.1. Receipt, adoption and audit of the guidelines (n=92)

Guideline topics	Recall receipt (%)	Adopted locally (%)	Used in local audit (%)
The preparation of the fetus for pre-term delivery	79 (86)	46 (50)	18 (20)
The management of mild, non-proteinuric hypertension	85 (92)	40 (43)	6 (7)
The management of pregnancy in women with epilepsy	86 (93)	53 (58)	13 (14)
The management of postpartum haemorrhage	78 (85)	47 (51)	23 (25)

4.4.3 The Preparation of the Fetus for Preterm Delivery

In response to direct questioning, all respondents reported prescribing antenatal steroids for women at risk of preterm delivery at baseline and follow up (Table 4.2). There was a statistically significant increase from 93% to 100% in the proportion correctly responding to the vignette. Most respondents suggested 24 weeks as the lowest gestation at which steroids would be

considered. There was less agreement on the highest gestational age at which steroids could be considered, reflected in responses to both direct questioning and the vignette. Compared with seven respondents who (appropriately) changed response to the avoidance of steroid therapy in a 28 year old primigravida presenting at 35 weeks gestation with PPROM, 17 changed their response to the prescribing of steroids.

Table 4.2. Guideline recommendations on the management of women at risk of preterm delivery, grade of recommendation and reported adherence.

Direct questions	**Baseline number (%)**	**Overall change from baseline (%)**	**P**
Prescription of ante-natal steroids for women at risk of pre-term delivery (n=83) Grade A	83 (100)	0 (0)	1
Lowest gestation of 24 weeks at which steroids would be considered (n=84) A	69 (82)	4 (5)	0.39
Highest gestational range of 34 to 36 weeks at which steroids would be considered (n=84) C	67 (80)	5 (6)	0.42
Use of tocolysis rarely to permit intra-uterine transfer to a tertiary centre or to allow a course of steroids to be administered and for a maximum period of 48 hours (n=83) A	67 (81)	12 (14)	0.004
Use of prophylactic antibiotics or entry to ORACLE trial in the management of women presenting with preterm, pre-labour rupture of the membranes (PPROM) (n=84) A	52 (62)	20 (24)	<0.0001
Vignettes and appropriate choices			
A 25 year old primigravida with insulin-dependent diabetes (IDDM) and a twin pregnancy at 28 weeks gestation at risk of delivery in the next 7 days.			
Initiation of steroid therapy (n=83) C	77 (93)	6 (7)	0.03
Usual dosage if initiating steroid therapy (n=78) A	72 (92)	3 (4)	0.45
Use of tocolytic therapy to allow steroid therapy to have an optimal effect, assuming that contractions are regular and painful, and that vaginal examination has indicated the cervix is 50% effaced and 3 cm dilated (n=84) A	55 (65)	10 (12)	0.07
Indomethacin as preferred drug for tocolysis in IDDM (n=67) B	27 (40)	4 (6)	0.06
A *28 yr old primigravida with no relevant medical or obstetric history presenting at 35 weeks gestation with PPROM*			
Avoidance of steroid therapy (n=83) C	62 (75)	-10 (-12)	0.06
Use of prophylactic antibiotic therapy or entry to ORACLE (n=84) A	44 (52)	23 (28)	<0.001

There was a significant reported increase in the appropriate use of tocolysis on direct questioning, although responses to the vignette were more conservative.

There was a significant reported increase in the consideration of prophylactic antibiotic therapy or entry to the MRC Preterm Antibiotic Uncertainty Study (ORACLE) in preterm pre-labour rupture of the membranes (PPROM). This increase occurred for both the direct question and vignette.

4.4.4 The Management of Mild, Non-proteinuric Hypertension in Pregnancy

There were no significant improvements in the management of mild, non-proteinuric hypertension from variable levels of baseline compliance (Table 4.3). At follow up, nearly a quarter of respondents (24%) did not report using Korotkoff phase IV (muffling of sounds) to measure diastolic BP. There was a non-significant increase in the proportion of respondents who would appropriately re-check a raised 'spot' diastolic BP. But over a quarter (26%) would inappropriately initiate investigations.

The guideline recommends that mild, non-proteinuric hypertension does not require anti-hypertensive therapy after 32 weeks gestation. Under this gestation, less than a third (28% at follow up) would consider treatment or refer to a colleague for advice. Over 32 weeks gestation, the majority (90% at follow up) of respondents would either avoid treatment or seek advice. There was little change from the low proportion preferring methyldopa as the first line agent for treating gestational hypertension (from 15% to 21%).

Just over half (53% at follow up) would monitor mild, non-proteinuric hypertension appropriately by checking BP and urinary protein twice weekly. A minority (20% at follow up) selected appropriate investigations for this condition. There was no change in the proportion of obstetricians reporting performing at least 4 out of the 5 basic investigations recommended in monitoring mild, non-proteinuric hypertension, with 50 (59%) doing so at baseline and 45 (53%) at follow-up (P=0.46).

Table 4.3. Guideline recommendations on the management of mild, non-proteinuric hypertension in pregnancy, grade of recommendation and reported adherence.

Direct questions	**Baseline number (%)**	**Overall change from baseline (%)**	**P**
Use of Korotkoff phase IV (muffling of sounds) in measuring diastolic BP (n=84) Grade C	58 (69)	6 (7)	0.21
Methyldopa as preferred first line agent for treatment, where appropriate, of gestational hypertension (n=85) B	13 (15)	5 (6)	0.23
Vignettes and appropriate choices			
A patient attending for routine antenatal care is found to have a "spot" diastolic BP of 95 mmHg but no proteinuria.			
Re-checking of BP within a short period and, if diastolic remains elevated, make arrangements for a further check in the hospital or community at least 4 hours later before initiating further investigations, n=86) C	55 (64)	9 (10)	0.09
A 20 year old primigravida at 34 weeks gestation develops gestational hypertension (diastolic BP consistently 95 mmHg) but no proteinuria.			
Avoidance of anti-hypertensive treatment or referral to a colleague for advice (n=86) A	73 (86)	4 (4)	0.42
A 20 year old primigravida at 31 weeks gestation develops gestational hypertension (diastolic BP consistently 95 mmHg) but no proteinuria.			
Consideration of anti-hypertensive treatment or referral to colleague for advice (n=85) A	21 (25)	3 (3)	0.63
A 20 year old primigravida with a diastolic BP of 95 mmHg but no proteinuria at 34 weeks gestation.			
Twice weekly (every 3-4 days) follow up for BP check and urine testing for (n=85) C	40 (47)	5 (6)	0.49
Selection of investigations for intermittent assessment of the above woman			
No more than two deviations from a list of 14 appropriate and inappropriate investigations. Appropriate tests are full blood count, platelet count, 'dipstick' testing for proteinuria, urea and electrolytes, and serum urate (n=85) C	16 (19)	1 (1)	1

4.4.5 The Management of Pregnancy in Women with Epilepsy

Seventy-nine respondents indicated that they provided care for pregnant women with epilepsy. Improvements in reported practice were more pronounced, with significant increases in the use of a higher dose of folic acid and combined administration of vitamin K (Table 4.4). Only 3 (4%) of respondents would not encourage breast feeding as for any other mother. There was less

consistency regarding the prescribing of oral contraception. Compared with 9 respondents who changed (appropriately) to including combined oral contraception in options offered to women on enzyme inducers, 20 subsequently would not.

Table 4.4. Guideline recommendations on the management of pregnancy in women with epilepsy, grade of recommendation and reported adherence.

Direct questions	**Baseline number (%)**	**Overall change from baseline (%)**	**P**
Periconceptual folic acid supplements at 4-5 mg/day (as for women with a previous history of neural tube defects) for women with epilepsy (n=78) Grade C	52 (67)	18 (23)	< 0.0001
Use of vitamin K 1 mg at birth for babies and treatment of mother with 20 mg orally daily from 36 weeks gestation for the prevention of haemorrhagic disease of the newborn (n=74) B	13 (18)	42 (57)	< 0.0001
Encouragement and support of breast feeding as for any other mother (n=76) B	67 (88)	6 (8)	0.07
Inclusion of combined oral contraception (COC) among the contraceptive options offered to women on enzyme inducers whilst encouraging the use of non-hormonal methods (n=79). B	42 (53)	-11 (-14)	0.06
Use of regimens containing higher doses of oestrogen as a first line when COC is chosen by a woman on an enzyme-inducing anticonvulsant. (Any of: 50 ug pill, combination of two lower dose pills or taking three or more packs of pills in succession without a pill-free interval, n=79) B	58 (73)	6 (8)	0.38

4.4.6 The Management of Postpartum Haemorrhage

Knowledge of recommendations for major obstetric haemorrhage from the 1991-3 CEMD Report did not consistently improve (177) (Table 4.5). Baseline knowledge was already high for 4 out of the 6 recommendations. There was a non-significant increase in the proportion of respondents who correctly recalled the need to order a minimum of two units of blood. But still only 50% recalled this at follow up. Similarly, only 53% at follow up correctly recalled the recommendation to set up central venous pressure (CVP) monitoring immediately. Compared with 10 respondents who changed (appropriately) to setting up CVP monitoring, 21 would no longer do so.

Table 4.5. Guideline recommendations on the management of postpartum haemorrhage, grade of recommendation and reported adherence.

True or false questions (and appropriate choice)	Baseline number (%)	Overall change from baseline (%)	P
Correct recall of recommendations made in the 1988-1990 Report on Confidential Enquiries into Maternal Deaths provided guidelines for the management of massive obstetric haemorrhage (n=86)			
Alert all of the following: anaesthetist, haematologist, blood transfusion and porters (true) Grade C	86 (100)	-1 (-1)	1
A minimum of 2 units blood should be ordered (true) C	31 (36)	12 (14)	0.06
Dextrans are recommended for transfusion until blood arrives (false) C	78 (91)	4 (4)	0.39
At least two intravenous lines should be set up using cannulae of not less than 14 gauge (true) C	86 (100)	-3 (-3)	0.58
Blood warming equipment is unnecessary (false) C	75 (87)	-6 (-7)	0.29
Central venous pressure monitoring should immediately be set up to ensure that therapy is safely controlled (true) C	57 (66)	-11 (-13)	0.07

4.5 Discussion

4.5.1 Main findings

Most obstetricians recalled receipt of the guidelines and around half stated that they had been adopted locally. Less than a quarter reported using each guideline for local clinical audit. Feedback of results from a baseline audit and dissemination of guidelines under the auspices of a national programme were followed by improvements in knowledge and self-reported obstetric practice.

Reported adherence to the guidelines increased significantly for recommendations in the guidelines concerning the management of anticipated preterm labour (despite relatively high baseline compliance) and women with epilepsy. However, considerable uncertainty persists regarding the optimal management of women with mild, non-proteinuric hypertension. There were wide variations in the reported frequency of follow up, selected investigations and therapeutic choices. For the management of postpartum haemorrhage, knowledge of relevant recommendations from the 1991-3 CEMD Report did not improve, partly because baseline knowledge was already high for majority of the recommendations.

4.5.2 Strengths and weaknesses

This project represented one of the first attempts to complement national clinical guideline development in Scotland with a related audit exercise. The results are consistent in direction and magnitude with those observed in previous national audit projects (34). However, improvements in practice cannot be directly attributed to the methods of audit and guideline dissemination for several reasons.

Some significant changes may have occurred by chance. At a significance level of 5%, at least one 'significant' change in practice will occur by chance following the multiple statistical tests performed in this study. Nevertheless, the overall trend was consistent with improved knowledge and practice and the limited number of obstetricians available for the survey probably constrained the ability to detect further significant changes.

Compliance with the guideline recommendations may have been over-estimated for two reasons. Firstly, 35% of the sample did not respond and obstetricians unaware of, or not following, the guidelines may have been less likely to respond to the survey (response bias). Secondly, self-reported practice may over-estimate actual clinical performance (37;129). Despite the confidential nature of the survey, some obstetricians may have consulted the guidelines to find the correct responses.

Other forms of bias related to the lack of a control group may have led to an over-estimation of the impact of the guideline dissemination strategy. Firstly, for the follow-up survey, those guideline recommendations with greatest scope for improvement in practice were selected. Regression to the mean occurs when study recommendations selected on the basis of their more extreme scores (low compliance with guideline recommendations) tend to give subsequent scores closer to the average. Secondly, maturation bias occurs when the passage of time brings about changes in clinical behaviour independent of the intervention. Clinicians may become more familiar with certain clinical practices over time independently of knowledge of the guideline recommendations (see 4.5.3 below). Thirdly, further problems may also occur in measuring outcomes over time. Clinicians responding to the follow-up questionnaire may have become sensitised to the most appropriate responses.

4.5.3 Meaning of the findings and possible mechanisms

Reported practice improved across most aspects of the management of anticipated preterm labour, notably in the appropriate use of steroid therapy, tocolysis and prophylactic antibiotics in PPROM. Significant improvements occurred despite high baseline compliance. This may have

reflected obstetricians' growing acceptance of a reliable evidence base (184) and, perhaps, synergistic (or co-interventional) effects of educational activities undertaken by the ORACLE study group around this time to promote the trial.

The reported improved management of pregnant women with epilepsy may reflect growing awareness of the special risks and needs associated with this group of women (185). It is also possible that characteristics of recommendations from this guideline influenced compliance (chapter 2). The relatively precise nature of the recommendations to use combined vitamin K regimens and the higher dose of folic acid supplement may have contributed to the observed significant changes in reported practice. The instances where sizeable proportions of clinicians shifted from compliant to non-compliant responses may be attributable to more ambiguous or complex recommendations, e.g. the inclusion of combined oral contraception as an option for women receiving enzyme inducers.

The 1994-6 CEMD Report indicated that pregnancy induced hypertension was the second most common cause of maternal mortality (159). The aggressive management of women with mild hypertension in pregnancy may reflect anxiety in missing or under-managing more serious disease. The guideline set out to support obstetricians in minimising clinical risk by offering a more structured, as well as efficient, approach to management. It is notable that 40 respondents (47% of 85) did not report the use of at least 4 out of the 5 basic investigations recommended in monitoring mild, non-proteinuric hypertension. One possible explanation for this is that the guideline's structured approach to minimise clinical risk possibly represented some of the more complex recommendations to follow, out of the four guidelines. Some established clinical practices are difficult to phase out. Less appropriate choices of investigation (such as the use of ultrasound) may have been influenced more by availability and women's preferences than by guideline recommendations.

Approximately half of respondents did not correctly recall the CEMD Report recommendations that a minimum of 2 units of blood should be ordered and that central venous pressure monitoring should be employed in the management of massive obstetric haemorrhage. However, responses to the baseline survey indicated that all Scottish maternity units had appropriate protocols in place. Rapid access to such protocols during clinical emergencies may be more important in improving standards of care than relying upon the limitations of memory (53).

4.5.4 Implications for clinical practice and policy

All of the guidelines have been updated, with no major changes, since their original publication. Given limited resources and the need to prioritise work within SPCERH's programme, these

findings suggest that further dissemination activities are probably not warranted for the guidelines on the preparation of the preterm fetus for delivery.

The reported improvements in the care of women with epilepsy contrast with the findings from a population based, prospective study in the English Northern health region (186). This study suggested that recommendations in the literature were still not being followed. Only 11% of women reported taking folic acid appropriately and Vitamin K was given as recommended to 36% of infants. Although from a different region, these findings suggest the need for greater scrutiny of the care of women with epilepsy based on a review of actual case note data rather than clinician self-reports.

Given the lack of improvement in self-reported management of mild, non-proteinuric hypertension and aspects of the management of post-partum haemorrhage, further dissemination activities would seem justified for these topics. Since this work, SPCERH has undertaken a national audit of the prevention and management of emergencies during labour (143). Of 411 cases of primary postpartum haemorrhage identified over 12 months (1999-2000), the care of 90% met at least 9 of 12 key criteria for good quality care based upon recommendations in the SOGAP guideline. All 12 criteria were met in only 6% of cases. Common deficiencies included the absence of 'hands-on' management by a consultant obstetrician in 55% of cases, the failure to site two or more intravenous lines in 44%, and cross-matching of blood for less than the (then) recommended six units of blood 74%. Following the audit, a national feedback meeting attended by representatives of Scottish maternity units made further recommendations to reinforce those from the CEMD Reports and SOGAP guideline.

4.5.5 Further research questions

This evaluation demonstrated acceptable levels of professional participation in an audit of four clinical practice guidelines. Nevertheless, the uncontrolled nature of this evaluation and the use of self-reported practice as an outcome measure greatly limited the attribution of changes in practice to the dissemination strategy. The next step therefore comprised a more rigorous evaluation of the strategy, an interrupted time series analysis, using actual patient data related to one of the guidelines (Chapter 5).

4.6 Conclusion

The dissemination and audit of clinical guidelines under a recognised national clinical effectiveness programme may contribute to consistent improvements in reported clinical practice.

Most obstetricians recalled receipt of the guidelines and around half stated that they had been adopted locally. Less than a quarter reported using each guideline for local clinical audit. There were significant improvements in the reported management of women at risk of preterm labour and those with epilepsy. Reported practice in relation to mild, non-proteinuric hypertension has improved little. This is possibly because this guideline was relatively complicated to understand and apply, and established patterns of practice are more resistant to change. More rigorous research methods are required to evaluate the effectiveness of this SPCERH dissemination strategy.

Chapter 5

Simple interrupted time series analysisof the impact of national obstetric guidelines on clinical practice

5.1 Summary

The clinical guideline, *The Management of Mild, Non-proteinuric Hypertension in Pregnancy*, was published in 1997 by the Scottish Programme for Clinical Effectiveness in Reproductive Health (SPCERH). Identified as a priority by clinicians, hypertension affects up to 10% of all women receiving antenatal care. The guideline encourages reductions in unnecessary hospital admissions and investigations, improved efficiency of care, and minimisation of disruption to women and their families. This study determined whether the dissemination of a clinical guideline under the auspices of a national clinical effectiveness programme had any impact on clinical practice and represented an efficient use of resources. It was planned and initiated prior to the post-intervention survey of obstetrician self-reported practice described in Chapter 4.

The design was a simple interrupted time series analysis. The intervention comprised distribution of the guideline under the auspices of SPCERH, supported by a national launch meeting and distribution of results of a baseline audit of obstetricians' reported practice.

Data were collected from four representative Scottish maternity units over a total of thirty-six months (24 months pre-intervention and 12 months post-intervention) between 1995 and 1998. The main clinical outcomes were the appropriateness of (i) initial investigation and (ii) subsequent clinical management, including the avoidance of unnecessary hospitalisation, investigations and treatments. An economic evaluation was planned to measure the costs and benefits of the guideline development, dissemination and implementation strategy.

The guideline was directly relevant to the 20.5% of women receiving antenatal care who experience an episode of raised diastolic blood pressure, proteinuria or both after 20 weeks gestation. The antenatal care of 1263 cases was assessed by a review of case notes. Care was consistent with the recommendations on initial investigation for 757 (59.9%) of women. A time series analysis indicated a non-significant increase of 10.6% in the compliance level (95% confidence interval -0.1 to 19.3%), which decreased by 1.2% per month post intervention (95% CI -2.5 to 0.1%).

Sufficient data were available on 1081 women to analyse clinical management, and 731 (67.6%) were considered to have been managed appropriately. The appropriateness of management

varied according to the required level of care. Compliance was highest (81.3%) for 739 women categorised as requiring routine antenatal care and lowest for the 143 requiring enhanced surveillance (4.9%). Women eligible for routine care tended to be over-investigated or seen at clinics too frequently. Those with clinical problems requiring closer surveillance tended to be under-investigated and attend clinics too infrequently. There was no evidence of a change in level in the appropriateness of clinical management (-0.3%; 95% CI -8.7 to 11.2%).

A cost-effectiveness analysis was not justified given the lack of any significant effects. The economic evaluation therefore focused on the costs of developing, disseminating and implementing the guideline. The total cost of the strategy was estimated at £66,809. The cost of guideline development accounted for 40% of the total costs whilst dissemination and implementation accounted for 60%. The average cost of the dissemination and implementation activities was estimated at £1695 per maternity unit in Scotland.

The most likely explanations for the lack of effect of the strategy are probably related to the nature of the guideline topic, the complexity of the guideline recommendations and the low intensity of the dissemination and implementation strategy.

5.2 Introduction

5.2.1 Hypertension in pregnancy

Hypertensive disorders of pregnancy comprise one of the major causes of maternal death in the UK, consistently ranking second to thrombo-embolism as a cause of direct maternal death (159). Hypertensive disorders are also associated with increased risks of stillbirth and neonatal death. Compared with normotensive women, proteinuric pre-eclampsia may carry a relative risk of 9.6 for stillbirth whilst diastolic hypertension alone is associated with a relative risk of 4.1 (187). Up to 6% of perinatal mortality in Scotland has been attributed to hypertensive disease (188).

The reports of the Confidential Enquiry into Maternal Deaths have repeatedly highlighted the need for clear guidelines for the management of severe hypertensive disorders and suitable protocols should already be in place in Scottish maternity units (177). Less attention has been paid to the management of mild, non-proteinuric hypertension in pregnancy. There is confusion about the relationships between various categories of mild disease and about their potential to progress to severe disease.

5.2.2 Development of the guideline

The guideline, *The Management of Mild, Non-proteinuric Hypertension in Pregnancy*, was produced as part of the Scottish Obstetric Guidelines and Audit Project (SOGAP) in response to these concerns. This guideline was systematically developed by a multidisciplinary group in accordance with Scottish Intercollegiate Guidelines Network (SIGN) methods of appraising and grading evidence (83). The guideline promoted the appropriate assessment and management of women with non-proteinuric hypertension, experienced by approximately 10% of all antenatal patients (i.e. 6,000 women per year in Scotland). The guideline addressed the following key aspects of care:

- Definitions and classification of hypertensive disease in pregnancy
- Prevention of gestational hypertension
- Assessment and appropriate levels of surveillance
- Pharmacological and other treatment strategies
- Place of management
- Management after delivery

Specifically, the guideline recommended that levels of care should be tailored to clinical findings (Table 5.1). Ideally, women should be able to move between levels of care according to their clinical progress.

Table 5.1. Recommended packages of care according to the guideline.

Care package	Eligible women	Components of care package
Routine antenatal care	'Spot' hypertension not sustained on assessment	
Basic surveillance	Confirmed mild hypertension	BP recording and urine 'dipstix' twice weekly; clinical appraisal of fetal size and well-being; single estimate of serum urate, urea and electrolytes, full blood count, platelets
Enhanced surveillance	Diastolic BP sustained at over 100mmHg or with mild hypertension and an incremental rise more than 25 mmHg since booking, clinical suspicion of poor fetal or maternal well-being or abnormal results on basic surveillance blood tests	BP recording and urine dipstix at least 3 times per week; weekly serum urate, U&Es, FBC, platelets, LFTs; scan assessment of fetal size and liquor volume; CTG assessment of fetal well-being
Specialist management (outwith guideline)	Severe hypertension, proteinuria, or abnormal findings during enhanced surveillance	Referral for specialist obstetric care

The guideline made other recommendations on clinical management. Neither inpatient admission nor induction of labour is indicated by mild, non-proteinuric hypertension (Grades B and C respectively). Anti-hypertensive drug treatment is not usually indicated for women with non-proteinuric gestational hypertension. Consideration may be given to anti-hypertensive therapy if hypertension has arisen before 32 weeks gestation or diastolic blood pressure rises to 100 mmHg or greater (Grade A recommendation). Ideally, drug treatment should comprise either labetolol or methyldopa (Grade B).

Use of the guideline should reduce unnecessary hospital admissions and over-investigation, improve the efficiency of care, and minimise disruption to women and their families. Furthermore, a structured approach to management should also enhance clinical risk management by (for example) improving detection of more severe hypertensive disease.

5.2.3 Dissemination and implementation of the guideline

The guideline was disseminated and implemented under the auspices of SPCERH (4.2.3). The impact of support from such a programme was uncertain and had not been formally evaluated. Furthermore, little work has previously assessed the cost-effectiveness of guideline development, dissemination and implementation. Given the opportunity costs of such activities within a clinical effectiveness programme, it is important to establish whether such costs are recouped by

resources saved following any change in clinical practice. This is particularly relevant where clinical guidelines may recommend reduced resource utilisation (such as the guideline on mild hypertension).

5.2.4 Previous work and pilot studies

Surveys of Scottish obstetricians' reported practice in 1997 and 1999 suggested that obstetricians appeared to investigate or admit women with mild, non-proteinuric hypertension at an inappropriately low threshold (Chapter 4). The uncontrolled nature of this evaluation and the use of self-reported practice as an outcome measure limited interpretation of these findings. The results of the post-intervention survey were not known during the time that a more rigorous evaluation of the dissemination and implementation strategy was being planned.

A preliminary survey of case notes was undertaken to pilot data collection for this study and estimate the proportion of eligible cases. 100 consecutive maternity notes covering deliveries during 1998 were assessed (40 from Aberdeen and 60 from Edinburgh). The guideline was applicable to 35 out of 100 cases examined. Compliance with a limited number of recommendations was assessed and revealed a mixed picture. For example, whilst blood pressure was often checked appropriately, the use of supporting investigations was inconsistent with evidence of excessive intervention in mild hypertension.

5.2.5 Research aim

This study aimed to determine whether dissemination of a clinical guideline on the management of non-proteinuric hypertension in pregnancy under the auspices of a national clinical effectiveness programme had any impact on clinical practice and represented an efficient use of resources.

5.3 Methods

A Steering Group was established to advise on study design and conduct and to consider the research findings (Appendix 5A).

5.3.1 Design

The research design was a simple interrupted time series analysis. Chapter 4 described the use of an uncontrolled before-and-after design to assess the impact of four clinical guidelines. Observations are made in one group before and after an intervention and observed differences attributed to the intervention (133). As discussed earlier (1.6.2) and illustrated in Figures 5.1 and

5.2, before-and-after studies may fail to account for underlying trends in practice. Therefore, improvements in practice may be over- or under-estimated.

Figure 5.1. Change in level of compliance for a before-and-after study.

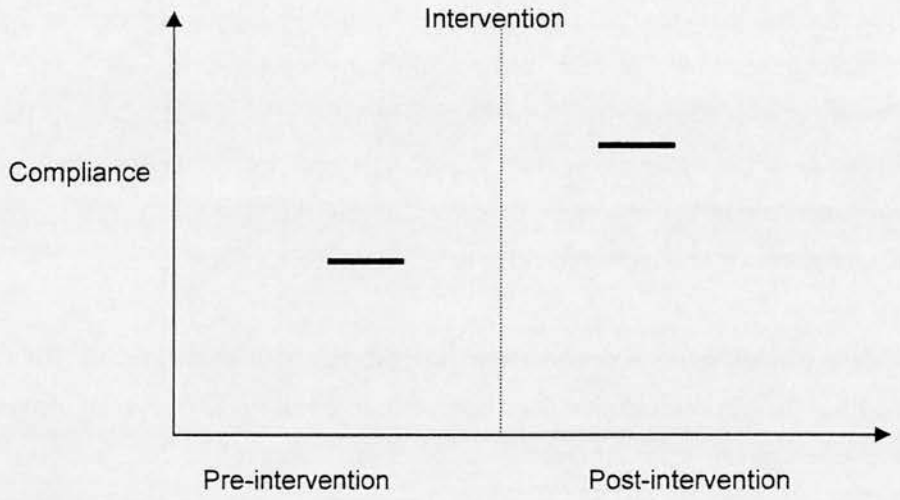
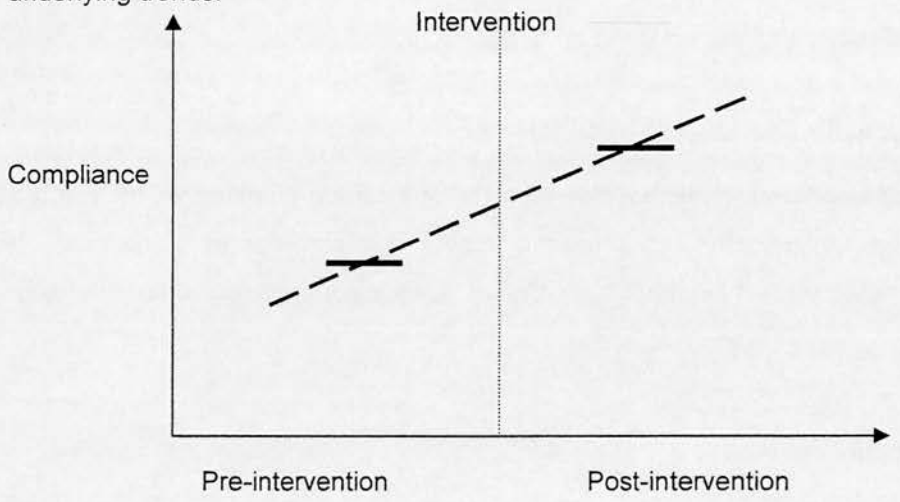


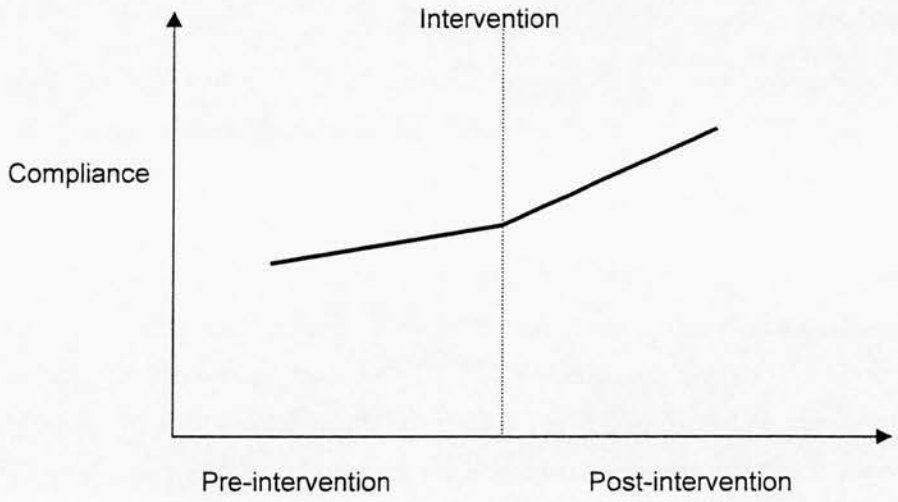
Figure 5.2. Change in level of compliance for a before-and-after study showing effect of underlying trends.



Interrupted time series analyses can detect whether an intervention had an effect significantly greater than the underlying (secular) trend (Figure 5.3). Such designs are appropriate in guideline implementation research for evaluating the effects of interventions when it is difficult to randomise or identify an appropriate control group. Data are collected at multiple time points before and after the intervention; the multiple time points before the intervention allow the underlying trend to be estimated, the multiple time points after the intervention allow the intervention effect to be estimated accounting for the underlying trend (189).

Simple (uncontrolled) time series analyses allow for secular changes resulting from maturation or regression to the mean to be estimated. The absence of a control group means that other sources of bias can undermine validity. Hence, for simple time series analyses, it is important to identify other factors that may influence outcomes in addition to the intervention, such as changes in instrumentation or external events.

Figure 5.3. Change in compliance in an interrupted time series.



The analysis of time series can be complex. Firstly, autocorrelation can occur, whereby the value of an observation at a given time point is related to the value of previous observations (190). Therefore ordinary statistical tests that assume observations are independent of each other cannot usually be used to compare (say) pre-intervention and post-intervention values. The effects of autocorrelation can be investigated and, if absent, the use of ordinary tests may be justified.

Secondly, interventions may have immediate or delayed effects. Many interventions, such as the dissemination of guidelines, may take time to diffuse and lead to a lag between intervention and effect. There should be a strong theoretical basis to support the attribution of changes in values to delayed effects of an intervention. The nature of the hypothesised effect should preferably be stated in advance of analysis to reduce the risk of false positive conclusions.

5.3.2 Study setting and participants

The study participants comprised obstetric units in two teaching (Aberdeen Maternity Hospital and Simpson Memorial Maternity Pavilion, Edinburgh) and two district general hospitals (Forth Park, Kirkcaldy, and Ayrshire Central Hospital, Irvine) in Scotland. Earlier plans to recruit Glasgow Royal Maternity Hospital as the fourth unit were abandoned because of problems gaining access to case notes when the hospital moved to a new site. The hospitals were selected

to balance geographical location and likelihood of compliance with the guideline (informed by responses to the questionnaires of self-reported practice – Chapter 4). In this way, it was intended to enhance the representativeness of the sampled hospitals.

The patient population consisted of women delivering a live or stillborn baby within each of the above four obstetric units during the study time periods.

5.3.3 Intervention

The guideline, *The Management of Mild, Non-proteinuric Hypertension in Pregnancy*, was one of four published and disseminated under the auspices of the Scottish Programme for Clinical Effectiveness in Reproductive Health (4.2.3). Activities comprised:

- A national meeting to launch the guideline attended by senior clinical representatives of all Scottish consultant-led obstetric units (March 1997). This meeting was also used to launch three other national obstetric guidelines (4.2.2). Two didactic presentations focused on hypertension in pregnancy; one on key points from the guideline; and the other on a profile of current practice. Delegates were able to choose from four interactive sessions, one of which covered the hypertension guideline.
- Distribution of results of a baseline audit of consultants' and specialist registrars' reported practice (October 1997). Feedback therefore took place at a national level. The feedback report highlighted what aspects of clinical care could be improved to comply with guideline recommendations
- Distribution of the clinical guideline itself to 7,700 health care professionals in Scotland, comprising all obstetric consultants and specialist registrars, all practising midwives, all general practice principals, and all consultant neonatologists (October 1997).

5.3.4 Outcomes

Two primary outcomes were developed, based upon compliance with guideline recommendations, to measure the appropriateness of diagnostic processes and subsequent clinical management.

Appropriateness of initial investigation of mild, non-proteinuric hypertension or proteinuria was to be judged according to the following criteria:

- Confirmation of mild hypertension by checking two BP measurements 4 – 24 hours apart;

- Investigation of proteinuria, including checking urine specific gravity for '+' proteinuria and investigating for infection.

Following a later review of the raw data – before any analysis of time trends - it became clear that applying the original criteria would leave a low proportion of cases categorised as appropriately investigated. Of 392 women who had their diastolic BP re-checked, only 172 (44%) were documented as having had it re-checked 4-24 hours later. It is likely that many women had their BP re-checked within 4 hours or did not have the timing of their assessments recorded. Therefore the requirements to meet this criterion were relaxed so that any documented re-checking was considered appropriate.

Similarly, of 635 women with documented proteinuria, only 2 (0.3%) were documented as having had specific gravity checked. The criteria required to meet this recommendation were also relaxed so that checking of specific gravity was no longer required to categorise care as appropriate.

These criteria were relaxed to enhance the subsequent sensitivity of the analysis. In the most extreme case, it would not be possible to detect any changes in the diagnosis of proteinuria if documentation of specific gravity was retained as a criterion. However, excessive relaxation of the criteria may undermine the validity of the compliance measures. The relaxation of the diagnostic criteria was considered justified given that the relevant recommendations were graded 'C' (i.e. based upon evidence from expert committee reports or opinions and/or clinical experience of respected authorities) and following discussions with the study's clinical advisors.

Appropriateness of management of women with a confirmed diagnosis of mild, non-proteinuric hypertension was initially based on the following criteria:

- Allocation of women to the recommended package of follow up care: routine antenatal care, basic surveillance, enhanced surveillance or specialist care (Table 5.1);
- Avoidance of hospitalisation (except for specialist care);
- Avoidance of interventions (anti-hypertensive therapy or induction of labour) after 32 weeks gestation (except for specialist care).

The assessment of compliance with the recommended packages of follow up care proved to be relatively complex. In particular, women could move between different levels of care over time, depending upon clinical findings and the results of investigations. Subsequently, collecting data to capture all relevant events over the complete course of a pregnancy would have been

prohibitively time consuming and difficult to analyse. The assessment of compliance with recommended packages of care therefore focused on the first seven days following the initial detection of raised BP, proteinuria or both. This restriction had implications for the measurement of other components of clinical management, namely the avoidance of inpatient admissions, induction of labour and inappropriate anti-hypertensive therapy.

Firstly, it was possible that a proportion of women with diagnosed mild, non-proteinuric hypertension developed more serious disease following the week of the initial diagnosis. Therefore, only admissions within that week were recorded and categorised as inappropriate unless specialist referral was indicated or the admission was for another stated indication.

Secondly, it was also originally planned to categorise induction of labour as inappropriate for all levels bar specialist care. However, as it was not possible to determine the appropriateness of subsequent induced labours, this criterion was removed.

Thirdly, the appropriateness of anti-hypertensive therapy was assessed using data collected beyond the week of the initial problem. The initiation of drug treatment was considered appropriate if hypertension was detected before 32 weeks gestation or DBP rose to 100 mmHg or greater. However, the avoidance of drug treatment was also considered appropriate in these circumstances. Therefore, inappropriate care comprised the use of drug therapy after 32 weeks gestation if DBP was less than 100 mmHg. Where drug therapy was considered justifiable, it had to consist of either labetolol or methyldopa to achieve compliance with the guideline.

Following a review of the raw data, the criteria for appropriate clinical management were modified – once again before the analysis of any time trends. When *all* of the criteria relating to the number of contacts, avoidance of inpatient admissions, conduct of investigations, and use of anti-hypertensive treatment were applied, compliance with the basic and enhanced surveillance care packages was virtually zero. This represented a notable finding in itself but reduced the ability of the planned time series to detect changes in practice.

For the definitive analysis, clinical management subsequent to the detection of raised blood pressure or proteinuria was categorised for four patient groups and appropriateness measured as in Table 5.2. The relaxation of these management criteria was justified on similar grounds to those for appropriate initial investigation. In addition, one recorded check of platelet levels was permitted for women receiving routine antenatal care. Platelet levels are frequently recorded as part of the full blood count and commonly used to diagnose or monitor anaemia.

Table 5.2. Appropriateness of care according to patient category.

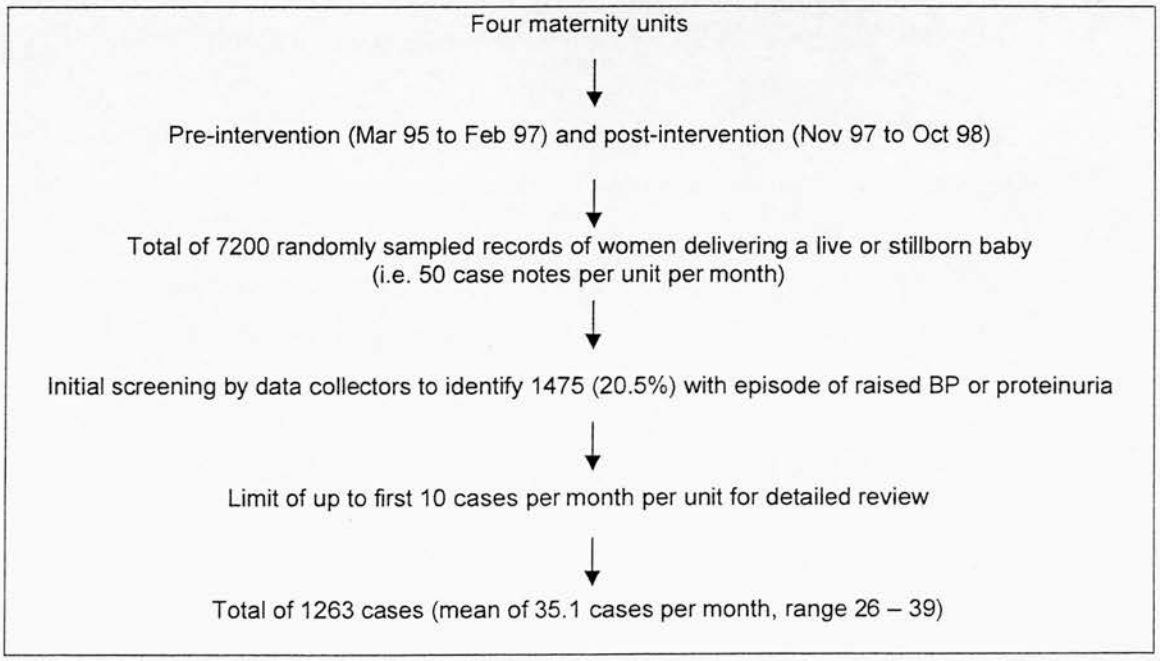
Patient category	Appropriate care
Routine antenatal care	At least two out of three criteria to be met for the following areas of care: number of contacts; investigations; and admissions
Basic surveillance	At least three out of four criteria to be met for the following areas of care: number of contacts; investigations; admissions; and anti-hypertensive treatment
Enhanced surveillance	At least three out of four criteria to be met for the following areas of care: number of contacts; investigations; admissions; and hypertensive treatment
Specialist care (outside scope of guideline)	Only documentation of being seen by an obstetrician required

5.3.5 Data collection

Identification of eligible cases. The aim of case identification was to identify a quota of cases for detailed review per month per maternity unit. The process is summarised in Figure 5.4. Data collectors screened case notes using a standard form (appendix 5B) to identify women who met at least one of the following criteria:

- Diastolic blood pressure (DBP) of 90 mmHg or greater recorded at any time after 20 weeks gestation;
- Proteinuria of '+' or greater recorded antenatally on one or more occasions after 20 weeks;
- Referral from primary care for further assessment of blood pressure or other evidence that the woman was managed for the assessment or treatment of mild hypertension.

Figure 5.4. Identification of eligible cases for assessment of appropriateness of care.



Case note review. Women hold their own antenatal records, which are completed following each visit for community or hospital care. Following delivery, these records are added to the hospital maternity case notes. These completed records formed the basis for the case note review. However, it was accepted that these records may not capture data from all contacts with relevant professionals in the community.

Data were collected from eligible cases on baseline characteristics, the processes of care occurring within the seven days of the detection of either raised diastolic blood pressure or proteinuria, and other aspects of management from twenty weeks gestation onwards.

Baseline data included:

- Age of the women at first visit
- Gestation at first visit
- Parity

Data on management within the seven days of first detection of raised diastolic blood pressure or proteinuria included:

- Initial and subsequent diastolic BP readings: urine dipstix testing, number of recorded clinical contacts
- Admissions (including recorded indications)
- Documentation of review by an obstetrician
- Investigations conducted (including documentation of abnormal findings).

From 20 weeks gestation onwards, data were collected on: usage, timing and type of anti-hypertensive therapy; and mode and outcome of delivery.

Case identification and data collection were piloted on 100 consecutive case records in two of the study hospitals. The final version of the data collection form is included in Appendix 5C.

Recruitment and training of data collectors. The recruitment of local data collectors was necessary to satisfy requirements from ethical committees and the Privacy Advisory Committee of the Information and Statistics Division (ISD) of the NHSiS. Data collectors consisted of clerical or midwifery staff from each of the four maternity units. All data collectors were visited and trained by the lead researcher (RF). These meetings covered the background to and objectives of the study, case identification and data collection. After data collectors had

extracted data from several case notes, their findings were compared with those of the lead researcher. This allowed identification and correction of several ambiguous items in the data collection form. All data collectors received an instruction booklet and a telephone number to contact in case of coding queries.

Economic evaluation. Cost data were elicited and estimated for the development, dissemination and dissemination of the guideline. The cost of development of the guideline included the costs of literature search, development group meetings, travel, writing up, and peer review. Also included in the development cost were the costs associated with organising the national launch (i.e. planning, venue, catering, and participants travel expenses) and the costs of the audit and feedback exercise which consisted of planning and performing the survey, and preparation and distribution of feedback. The costs of dissemination were made up of the costs of printing and postage incurred in the distribution of the guideline.

Cost estimates were derived from SPCERH records and local sources. Staffing costs of GPs, doctors, and midwives were taken from standard sources (191-193). Average costs per woman attending a maternity unit and per woman to whom the guideline directly applied (i.e. with an episode of raised diastolic blood pressure or proteinuria) in Scotland were calculated. Estimates of women attending maternity units were taken from ISD Scotland. Estimates of the women to whom the guideline directly applied were taken from the study case identification data. Similar average costs were also presented for the four maternity units that contributed data to the time series analysis. Resource use and unit costs, expressed in 2001 values, are displayed in Appendix 5D.

The outcomes comprised the degree of behaviour change according to the two primary outcomes outlined above (2.4). The cost-effectiveness of implementing this particular guideline depended upon the cost-effectiveness of the interventions recommended by the guidelines. This approach is recommended for evaluating the implementation of guidelines (90). To address this, it was planned to ascertain NHS resource use from the case note review and estimate health benefits from the literature review supporting the guideline.

5.3.6 Sample size

Given uncertainties in calculating sample sizes for time series analyses, it is acknowledged that the number of time points and number of cases per time points were chosen largely on pragmatic grounds (194;195). Twenty-four monthly (2 years) pre-intervention data sampling points were necessary to judge any preceding trends or seasonality (periodicity) in clinical management. By considering 24 months, each calendar month was studied twice, thereby allowing seasonal effects

to be investigated statistically. A further twelve monthly points were required post-intervention to assess any changes in clinical management. Up to forty cases per month (10 per maternity unit) were considered necessary to provide sufficiently reliable estimates of compliance per time point. Forty cases per month gave the study 80% power at 5% significance to estimate the proportion compliant at each time point to within 15%. This equated to a total planned sample size of 1440 cases.

For each maternity unit to contribute 10 cases per month, it would be necessary for the data collectors to screen an average of 33 case notes per month (based on the pilot study). To allow for random sampling variability and missing case notes, 50 case notes per month were sought for screening. The sampling frame was drawn from Scottish Maternity Record (SMR) 02 statistics following permission from the Privacy Advisory Committee of the ISD. As the guideline was disseminated between March and October 1997, eligible cases were sought with dates of delivery:

- 1st March 1995 to 28th February 1997
- 1st November 1997 to 31st October 1998

Fifty case numbers per hospital per month were randomly selected from the centrally held SMR 02 data. This equated to a total of 7200 case numbers. Only one delivery per patient was extracted.

Where more than 10 eligible cases were identified within a month in an individual maternity unit, the detailed case note review was limited to the first 10 cases. This limit was both based upon the sample size calculation and the need for the costs of study to remain within given resources.

5.3.7 Data entry

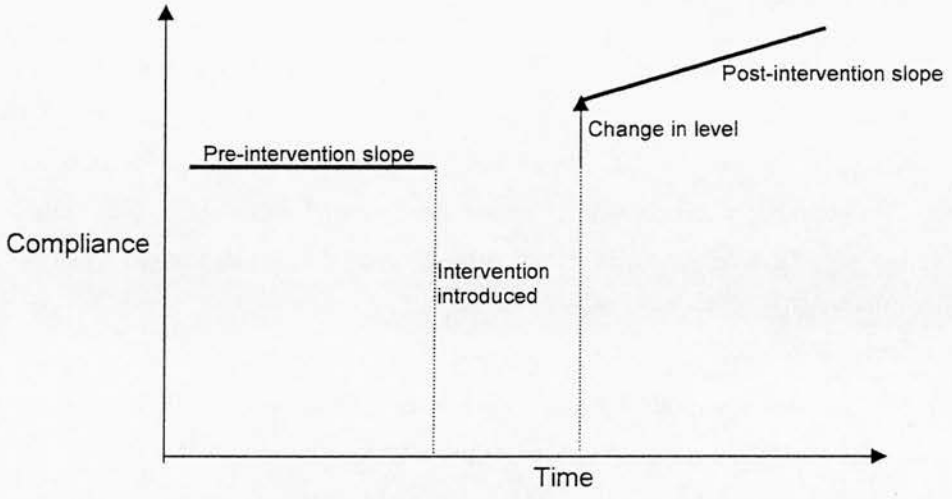
Data were entered into an Access Database. The reliability of data entry was checked by re-entering data for ten variables for a 5% random sample of questionnaires (n=64). Three miscoding errors were detected out of a total of 640 entries. As two of these comprised the same miscoding error the whole database was searched for their occurrence. Eight further similar errors were detected and the data entries corrected.

5.3.8 Analysis

Time trends. Compliance with recommendations was measured according to the criteria set out in section 5.3.4 and detailed in the algorithms in Appendix 5E.

Following visual inspection of time trends in compliance, a logistic regression model that adjusted for the clustering per time point was fitted. Robust standard errors (SEs) were calculated using time period as a clustering effect. The results of the logistic regressions were given in terms of odds ratios. The odds ratios were also transformed to give estimates of level and post-intervention slope in terms of percentage change using the predicted values from the model fitting procedure (illustrated visually by Figure 5.5). Autocorrelation for the compliance outcomes were investigated using the autocorrelation and partial autocorrelation functions.

Figure 5.5. Parameters assessed by the interrupted time series.



It would be naïve to expect any change in clinical practice immediately following dissemination and implementation of the guideline. However, it was anticipated that any observable effects should start to occur within the first half of 1998 (the follow up year), by which time any relevant educational activities and incorporation into local protocols should have occurred. The impact of potentially confounding events was considered in the interpretation of the analysis. National or local activities (e.g. local audit, publication of reports) that might influence clinical behaviour were defined as confounding events. If prompted primarily by dissemination and implementation of the guideline, such activities became in effect an extension of the whole intervention.

In addition to changing levels of compliance, it was also possible that dissemination and implementation of the guideline reduced variability between time points, i.e. clinical practice became more uniform. Therefore, a t-test was performed on the mean compliance per time point and Levene's test for equality of variances (pre to post) was used to identify whether any such effects occurred.

Economic evaluation. Two phases of the economic evaluation were planned. Phase one would compare the costs of implementation with the degree of behaviour change occurring. This would help model the cost-effectiveness of national clinical effectiveness programmes to disseminate other guidelines. For phase two, it was planned to present the data collected as a balance sheet if the intervention demonstrated any effect. The balance sheet allows different health effects to be weighed against each other and against net cost, thereby making explicit the choices and trade-offs implicit in a policy decision (196).

5.4 Results

5.4.1 Number of cases identified

Out of 7200 case notes screened, 1475 (20.5%) were identified as having had a raised DBP reading, proteinuria or both over the study period (Table 5.3). The total number of cases identified per maternity unit ranged from 299 to 464. The reasons for these differences are not known but may reflect random sampling error or a combination of variations in data collectors' abilities to detect eligible cases, availability of clinical data in the four formats of unit case records and the true incidence of eligible cases.

When the limit of ten cases per hospital per month was applied, a total of 1263 cases were available for detailed analysis, a mean of 35.1 cases per month with a range of 26 to 39. Table 3 shows the breakdown in the number of cases assessed by maternity unit.

Table 5.3. Number of cases identified for analysis by unit.

Maternity unit	Number of cases screened	Number of cases identified	Number of cases sampled
A	1800	379	334
B	1800	333	308
C	1800	299	281
D	1800	464	340
Total	7200	1475	1263

5.4.2 Characteristics of study sample

Table 5.4 shows the characteristics of the study sample. A total of 433 (34.3%) of women had induced labours, of which 183 (14.5%) were recorded to be indicated by hypertension. A total of 285 (22.6%) of women underwent caesarean section, of which 60 (4.8%) were recorded to be indicated by hypertension.

Table 5.4. Characteristics of study sample

Characteristic	Number or proportion
Median age of women at booking (Inter-quartile range, IQR)	28 (24-31)
Median number of previous completed pregnancies (IQR)	0 (0-1)
Median number of miscarriages and induced abortions	0 (0-1)
Median gestation at delivery (IQR)	40 (38-40)
Proportion of induced labours (n=1263)	34.3%
- induced for hypertension	14.5%
- induced for other or unstated indications	19.8%
Proportion of caesarean sections (n=1263)	22.6%
- indicated by hypertension	4.8%
- other or unstated indications	17.8%

The study sample was assessed to detect any changes in basic demographic and clinical characteristics over time. Appendix 5F presents tables of the number of cases, mean age at first visit, mean parity (completed and uncompleted pregnancies), gestation, proportion with raised diastolic episode and proportion with proteinuria episode broken down by month and maternity unit. These data suggest no temporal trends in patient characteristics over the study period.

5.4.3 Appropriateness of initial investigation

5.4.3.1 Overall compliance

Out of a total of 1263, care was consistent with the recommendations on the initial investigation for 757 (59.9%) of women (Table 5.5). Out of the 653 with an abnormal diastolic BP reading, 381 (58.3%) underwent appropriate initial investigation. Out of the 635 with proteinuria of + or greater, 396 (62.4%) underwent appropriate initial investigation. Compliance ranged from 46 to 69% among the four maternity units (Table 5.6). This range may reflect true or random variations in compliance, although it is possible that data were abstracted differently in unit D.

Table 5.5. Compliance with criteria for appropriate initial investigation.

Outcomes	Number eligible	Number compliant	Percentage compliance
Detection and initial investigation of high diastolic blood pressure	653	381	58.3
Detection and initial investigation of proteinuria	635	396	62.4
Overall compliance	1263*	757	59.9

*The total does not come to 1288 because 25 women experienced high diastolic BP readings and proteinuria simultaneously.

Table 5.6. Compliance with criteria for appropriate initial investigation by maternity unit.

Outcomes	Number eligible	Number compliant	Percentage compliance
A	334	221	66.2
B	308	186	60.4
C	281	193	68.7
D	340	157	46.2
Overall compliance	1263	757	59.9

5.4.3.2 Time series analysis

Visual inspection. Figure 5.1 shows the graph of mean compliance with the diagnostic criteria, with corresponding 95% confidence intervals broken down by month. Visually, there appears little evidence that there was a change in level or slope for initial investigation but there is the possibility of a downward trend in the last six months of the data. The percentage compliance rates for initial investigation broken down by hospital and month are presented in Table 5.7.

Outliers were identified. Figure 5.6 shows that the level of compliance for initial investigation was low for months 11 and 12. This was due to low compliance in two units (B and D) during these months.

Figure 5.6. Time series of percentage compliance and 95%CI for initial investigation.

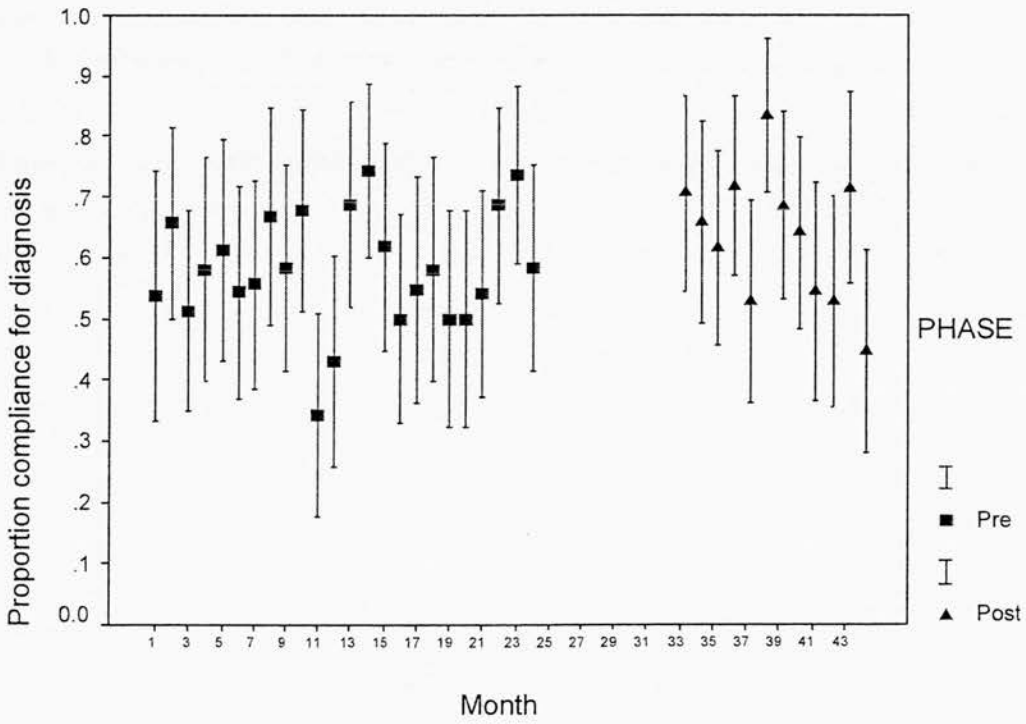


Table 5.7. Percentage compliance with criteria for appropriate initial investigation by month and hospital

Month	A (n=334)	B (n=308)	C (n=281)	D (n=340)	All hospitals (n=1263)
1	50	63	33	56	54
2	40	67	90	67	66
3	70	50	56	30	51
4	83	50	78	30	58
5	56	29	100	70	61
6	50	44	83	50	54
7	50	63	67	44	56
8	80	60	100	00	67
9	70	75	63	30	58
10	89	56	67	57	68
11	50	50	33	10	34
12	50	25	50	44	43
13	67	56	100	56	69
14	80	78	80	60	74
15	80	100	50	40	62
16	90	50	20	38	50
17	50	60	67	50	55
18	40	83	60	60	58
19	50	20	100	56	50
20	29	50	86	40	50
21	60	56	75	30	54
22	80	67	67	60	69
23	60	80	89	67	74
24	80	50	67	29	58
Intervention					
25	90	86	71	40	71
26	70	80	60	50	66
27	50	70	67	60	62
28	80	40	89	80	72
29	80	56	56	20	53
30	78	80	100	80	83
31	60	70	100	50	68
32	70	78	70	40	64
33	56	60	67	45	54
34	80	67	30	40	53
35	90	100	67	40	71
36	56	50	56	20	45

Pre-post analysis (ignoring trend effects). The percentage compliance overall and by hospital is shown in Table 5.8. There was a non-significant increase in the appropriateness of diagnostic processes, with an overall increase of 5.3% (p=0.075). This analysis, however, did not take into account possible trends in the data.

Table 5.8. Pre- and post-intervention compliance with criteria for appropriate initial investigation.

	Pre-intervention compliance	Post-intervention compliance	Difference	P-value
Overall	58.1	63.4	+5.3	0.075
Unit				
A	63.1	71.8	+8.7	0.140
B	56.2	68.2	+12.0	0.054
C	68.8	68.4	-0.4	0.946
D	45.7	47.1	+1.4	0.887

Changes in variability. To test for a possible change in the variability of the percentage compliance point estimates per month (see visual inspection above), a t-test was performed and Levene's test for equality of variances (pre to post) was used. There was no evidence that the variability of the mean compliance with the diagnostic criteria changed (Levene's test: $F = 0.351$; $p = 0.558$), i.e. clinical practice did not become more uniform following dissemination of the guideline.

Logistic regression modelling. Table 5.9 presents the results of the logistic regression. This indicates a non-significant increase of 10.6% in the compliance level (95% confidence interval -0.1 to 19.3%), which decreased by 1.2% per month post intervention (95% CI -2.5 to 0.1%). The autocorrelation and partial autocorrelation functions did not display any evidence of autocorrelation in the series.

Table 5.9. Trends in appropriateness of initial investigation analysed by logistic regression adjusted for the clustering per time point.

	OR	(95% CI)	P	% change	(95% CI)
Slope	0.941	(0.883, 1.000)	0.058	-	-
Level	1.587	(0.995, 2.531)	0.053	10.6	(-0.1, 19.3)
Post slope	0.946	(0.891, 1.005)	0.073	-1.2	(-2.48, 0.1)

5.4.4 Appropriateness of clinical management

5.4.4.1 Overall compliance

Sufficient data were available on 1081 cases to enable an analysis of the appropriateness of clinical management. Overall, management was appropriate for 749 (69.3%) of cases (Table 5.10). The appropriateness of management varied according to the required level of care. Compliance was highest (81.3%) for the 739 women categorised as requiring routine antenatal care and lowest for the 143 requiring enhanced surveillance (17.5%). Compliance varied among maternity units, ranging from 64.8 to 73.4% (Table 5.11).

Table 5.10. Compliance with appropriate clinical management.

Outcomes	Number eligible	Number compliant	Percentage compliance
Routine care: at least two out of three criteria met	739	601	81.3
Basic surveillance: at least three out of four criteria met	43	20	46.5
Enhanced surveillance: at least three out of four criteria met	143	25	17.5
Specialist care: criterion met	156	103	66
Overall compliance	1081	749	69.3

Table 5.11. Compliance with appropriate management by maternity unit.

Unit	Number eligible	Number compliant	Percentage compliance
A	299	208	69.6
B	250	162	64.8
C	246	169	68.7
D	286	210	73.4
Overall compliance	1081	749	69.3

5.4.4.2 Explaining non-compliance

The data were explored to determine the main reasons for non-compliance with the guideline recommendations on appropriate levels of care.

Routine care. Overall compliance with routine care was 81.3% based upon meeting at least two out of three criteria (Table 5.12). Avoidance of unnecessary investigations was the criterion least frequently met (69%). Serum urea and electrolytes was the most frequently conducted inappropriate test, being carried out at least once in 91 (12.3%) women.

Table 5.12. Compliance with criteria for appropriate routine care (n=739)

Criteria and outcomes	Number compliant	Percentage compliance
1 to 2 contacts within seven days	642	86.9
No in-patient admission or admission for labour	621	84.0
Avoidance of unnecessary investigations	510	69.0
All three criteria met	463	62.7
At least two out of three criteria met	601	81.3

Basic surveillance. Overall compliance with basic surveillance was 46.5% based upon meeting at least three out of four criteria (Table 5.13). No cases met all four criteria. No women were investigated appropriately. This was mainly because of failures to perform (or record) blood

tests. Thirty-seven women (86%) had no serum urea and electrolytes performed, 36 (83.7%) no serum urate, and 32 (74.4%) no platelet counts. Amongst other criteria, 9 women (20.9%) had only one documented clinical contact within that week and eight women (18.6%) had over three contacts.

Table 5.13. Compliance with criteria for basic surveillance (n=43).

Criteria and outcomes	**Number compliant**	**Percentage compliance**
2 to 3 contacts within seven days	26	60.5
No in-patient admission or admission for labour	36	83.7
Appropriate investigations	0	0
Appropriate anti-hypertensive treatment	41	95.3
All four criteria met	0	0
At least three out of four criteria met	20	46.5

Enhanced surveillance. Overall compliance with enhanced surveillance was 17.5% based upon meeting at least three out of four criteria (Table 5.14). No cases met all four criteria. Only one woman (0.7%) was investigated appropriately. Again, this was mainly because of failures to perform (or record) blood tests. Eighty-eight women (61.5%) had no serum urea and electrolytes performed, 95 (66.4%) no serum urate, 71 (49.7%) no platelet counts, and 119 (83.2%) no liver function tests.

Amongst other criteria, 93 women (65.1%) had less than three documented clinical contacts within that week, and 53 (37.1%) were admitted for hypertension or another indication (except labour). However, in 139 cases (97.2%), anti-hypertensive treatment was initiated or withheld appropriately.

Table 5.14. Compliance with criteria for enhanced surveillance (n=143)

Criteria and outcomes	Number compliant	Percentage compliance
3 to 4 contacts within seven days	41	28.7
No in-patient admission or admission for labour	90	62.9
Appropriate investigations	1	0.7
Appropriate anti-hypertensive treatment	139	97.2
All four criteria met	0	0
At least three out of four criteria met	25	17.5

Specialist care. As specialist care was outside the scope of the guideline, the only criterion to be met was documented contact with an obstetrician. This was not met for 53 (34%) of relevant cases.

5.4.4.3 Time series analysis

Visual inspection. Figure 5.7 shows the graph of percentage compliance with the criteria for appropriate management. Visually, there appears little evidence that there was a change in level or slope. The graph does suggest a decrease in variability for management of cases as the proportions appear closer together post- compared to pre-intervention). The compliance percentages broken down by hospital and month are presented in Table 5.15.

Figure 5.7. Times series of percentage compliance and 95%CI for clinical management of patients.=

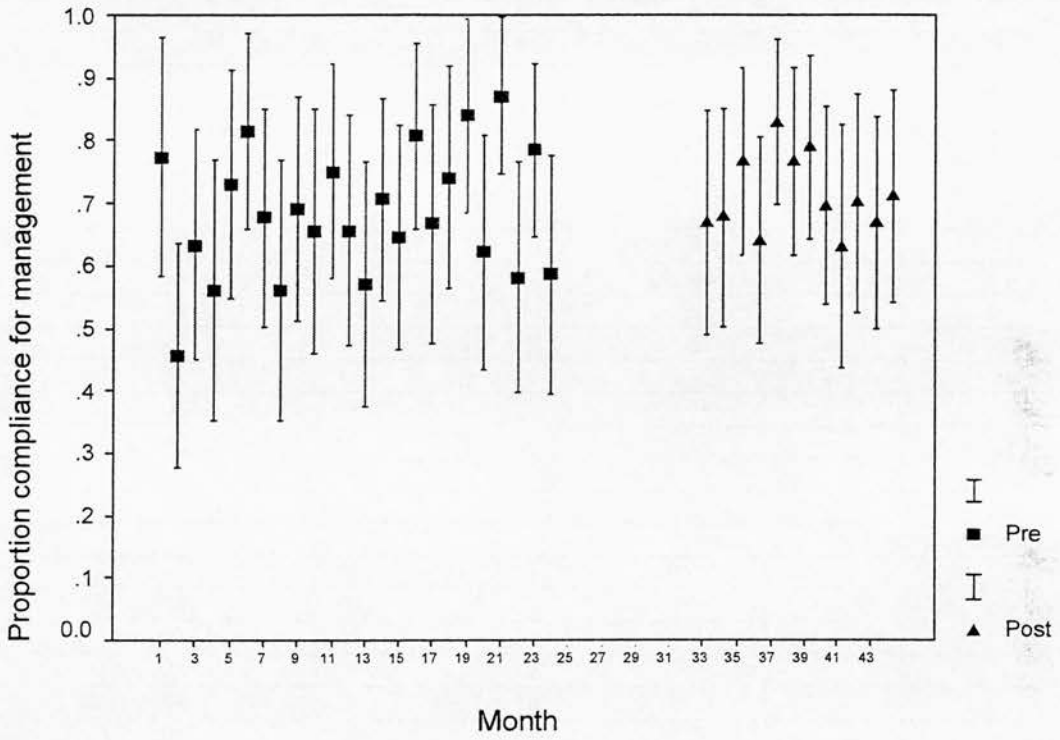


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Table 5.15. Percentage compliance with criteria for appropriate management by month and hospital.

Month	A (n= 299)	B (n= 250)	C (n= 246)	D (n= 286)	All hospitals (n=1081)
1	100	71	100	63	77
2	43	13	44	78	45
3	56	75	60	63	63
4	83	60	25	67	56
5	83	100	60	60	73
6	75	100	83	78	81
7	88	71	63	50	68
8	70	38	50	100	56
9	43	67	75	88	69
10	100	17	63	80	65
11	80	57	88	75	75
12	71	67	44	86	66
13	60	29	63	75	57
14	67	71	50	90	71
15	44	100	88	50	65
16	60	100	75	100	81
17	60	50	75	78	67
18	100	100	60	44	74
19	75	83	100	83	84
20	71	71	43	63	62
21	90	75	100	80	87
22	67	56	50	56	58
23	70	70	100	75	78
24	44	57	88	40	59
Intervention					
25	70	71	86	33	67
26	56	70	50	88	68
27	67	90	50	100	76
28	67	44	56	89	64
29	100	63	88	80	83
30	67	63	86	90	76
31	75	89	75	75	79
32	70	63	75	70	69
33	57	63	0	80	63
34	60	60	75	86	70
35	60	60	75	70	67
36	78	33	83	80	71

Pre-post analysis (ignoring trend effects). The percentage compliance overall and by hospital is shown in Table 5.16. There was a small (3.7%) statistically non-significant change in management, not accounting for possible trends in the data. Compliance fell by 2.3% in unit A whilst compliance increased by 10.2% in unit D.

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Table 5.16. Pre- and post-intervention compliance with criteria for appropriate management.

	Pre-intervention compliance	Post-intervention compliance	Difference	P-value
Overall	66.3	70.0	+3.7	0.235
Unit				
A	68.4	66.1	-2.3	0.770
B	63.1	65.6	+2.5	0.789
C	66.3	71.1	+4.8	0.534
D	66.9	77.1	+10.2	0.088

Changes in variability. The variability of the mean compliance with the criteria for appropriate management did not significantly change (Levene's test: $F = 3.283$; $p = 0.08$).

Logistic regression modelling. Table 5.17 presents the results of the logistic regression. There was no evidence of a change in level in the appropriateness of clinical management (-0.3%; 95% CI -8.7 to 11.2%). The autocorrelation and partial autocorrelation functions did not display any evidence of autocorrelation in the series.

Table 5.17. Trends in appropriateness of management analysed by logistic regression adjusted for the clustering per time point.

	OR	(95% CI)	P	% change	(95% CI)
Slope	0.973	(0.926, 1.023)	0.28	-	-
Level	0.968	(0.554, 1.692)	0.91	-0.3	(-8.7, 11.2)
Post slope	0.995	(0.995, 1.029)	0.65	-0.2	(-1.1, 0.3)

5.4.5 Economic evaluation

5.4.5.1 Costs of the guideline strategy

The total guideline development, dissemination and implementation cost was estimated at £66,809 (Table 5.18). The cost of guideline development was estimated at £26,142, accounting for 40% of the total costs. The dissemination and implementation costs of £40,670 amounted to 60% of the total costs. Two-thirds (67%) of these costs were driven by the national launch meeting.

Direct costs of staffing (time of research staff and health care professionals) and indirect costs of staffing (costs of travel and catering) made up 85% of total costs. Other costs related to literature search, printing and posting the questionnaire did not contribute substantially to the development, dissemination and implementation of the guideline.

Table 5.18. Costs of guideline development, dissemination and implementation (2001 values).

Component	Resources	Cost (£)	Percentage of total costs
Guideline development		26,142	40
	Literature search	200	0
	Development group meetings	6,416	10
	Travel	1,080	2
	Writing up	17,811	27
	Peer review	635	1
Dissemination and implementation			
National launch meeting		26,400	40
	Planning	1,782	3
	Venue	685	1
	Catering	609	1
	Participants	23,324	35
Audit and feedback		7,298	10
	Planning	1,484	2
	Survey	2,790	4
	Feedback	3,024	4
Distribution of guideline		6,972	10
	Printing	5,124	7
	Postage	1,848	3
TOTAL		66809	100

5.4.5.2 Mean costs of the guideline strategy

The guideline was valid for a period of three years and applied to all women attending a maternity unit for antenatal care in Scotland. Alternatively, it could be argued that the guideline was mainly relevant to women experiencing episodes of raised diastolic blood pressure or proteinuria in Scotland. The proportion of women to whom the guideline directly applied was taken as 20.5% (1,474 / 7,200), obtained from the case note review component of the study reported earlier. The mean costs of the guideline strategy were estimated for these two alternatives (i.e. all women and those to whom the guideline applied directly).

In the former case, it was assumed that approximately 155,800 women would attend a maternity unit in Scotland over the next three years in Scotland. While in the latter situation it was assumed that the guideline would be directly relevant to approximately 32,000 women during the same time period. These data were combined with the total cost data presented in Table 5.19 to provide mean costs. The mean cost of the dissemination and implementation activities was £1695 per maternity unit in Scotland. The mean guideline strategy cost per maternity unit was £2,784. The associated mean cost per woman attending for antenatal care was £0.43 whilst that per woman with an episode of raised diastolic blood pressure or proteinuria was £2.09.

Also shown in Table 5.19 is the mean cost per woman in each of the four hospitals that contributed data to the time series analysis. It was assumed that the cost of the guideline was evenly distributed across the 24 hospital maternity units in Scotland. The number of women in each department was obtained from ISD Scotland. The mean cost per woman attending for antenatal care ranged from £0.44 to £0.94. The mean cost per woman with an episode of raised diastolic blood pressure or proteinuria ranged from £2.23 to £4.59.

Table 5.19. Mean costs of the guideline.

Guideline applies to	Cost	Number of women	Cost of developing and disseminating the guideline per woman
All women	£66809	155,800	£0.43
Women to whom the guideline directly applied	£66809	32,000	£2.09
All women (four recruiting hospitals A to D only)			
A	£2,784	4,208	£0.66
B	£2,784	3,537	£0.79
C	£2,784	6,099	£0.46
D	£2,784	2,961	£0.94
Women to whom the guideline directly applied (four recruiting hospitals A to D only)			
A	£2,784	861	£3.23
B	£2,784	724	£3.85
C	£2,784	1249	£2.23
D	£2,784	606	£4.59

5.5 Discussion

5.5.1 Main findings

This interrupted time series analysis assessed the impact of dissemination and implementation of the clinical guideline, *The Management of Mild, Non-proteinuric Hypertension in Pregnancy*. The guideline was directly applicable to 20.5% of women receiving antenatal care who experience an episode of raised DBP or proteinuria after 20 weeks gestation.

The antenatal care of 1263 pregnant women experiencing an episode of raised DBP, proteinuria or both was assessed by a review of case notes. Data were collected from four Scottish maternity units over a total of thirty-six months (24 months pre-intervention and 12 months post-intervention) between 1995 and 1998.

Care was consistent with the criteria for the initial investigation of raised DBP or proteinuria for 757 (59.9%) of women. Out of 653 with an abnormal diastolic BP reading, 381 (58.3%) underwent appropriate initial investigation. Out of 635 with proteinuria, 396 (62.4%) underwent

appropriate initial investigation. The time series analysis indicated a non-significant increase of 10.6% in the compliance level (95% confidence interval -0.1 to 19.3%), which decreased by 1.2% per month post intervention (95% CI -2.5 to 0.1%).

Sufficient data were available on 1081 women to analyse clinical management, assessed as appropriate for 731 (67.6%). The appropriateness of management varied according to the required level of care. Compliance was highest (81.3%) for 739 women categorised as requiring routine antenatal care and lowest for the 143 requiring enhanced surveillance (17.5%). Women eligible for routine care tended to be over-investigated or seen at clinics too frequently. Those with clinical problems requiring closer surveillance tended to be under-investigated or attend clinics too infrequently. However, in the majority of women requiring enhanced surveillance (97.2%), anti-hypertensive treatment was initiated or withheld appropriately. There was no evidence of a change in level in the appropriateness of clinical management (-0.3%; 95% CI -8.7 to 11.2%).

Given the lack of any significant effects, the economic evaluation focused on the costs of guideline development, dissemination and implementation. The total cost was estimated at £66,809. The cost of guideline development accounted for 40% of the total costs whilst dissemination and implementation activities accounted for 60%. These costs were dominated by the national launch meeting. The mean cost of dissemination and implementation was £1695 per maternity unit in Scotland. For the guideline strategy, the mean cost per woman with an episode of raised DBP or proteinuria ranged from £2.23 to £4.59 in the four study hospitals.

5.5.2 Strengths and weaknesses of study

This study design met all eight of the quality criteria for interrupted time series designs recommended by Ramsay et al (134).

The intervention occurred independently of other changes over time. Potentially confounding local and national events were investigated over the study period. Local clinical and audit staff were contacted to identify relevant local activities. No relevant clinical audits were held or local protocols introduced within the study period. An educational meeting for GPs, which covered the mild hypertension guideline, was held in Aberdeen in November 1998. This was judged to represent a local extension of the national dissemination strategy rather than a confounding event.

The newsletter of the RCOG was screened for relevant national meetings. Two were identified: a meeting of the International Society for the Study of Hypertension in Pregnancy (Oxford, September 1997); and an RCOG study day on pregnancy induced hypertension (Oxford, October

1997). These both occurred within the intervention period. It was not possible reliably to identify whether any clinicians from the study hospitals had attended either of these meetings. It was judged highly unlikely that these meetings would have exerted any significant impact on practice within the study hospitals, especially given the relatively small effects of educational meetings (197).

The most relevant national publication over the study period was the Report of the Confidential Enquiries into Maternal Deaths published in June 1996 – or month 16 of the time series (177). The report highlighted the importance of detecting severe hypertensive disease and stressed the need for early consultant involvement and local guidelines. According to Figure 1, compliance with the criteria for initial investigation dropped slightly over month 16 and increased over the subsequent two months. In contrast, Figure 2 shows that compliance with management criteria peaked during month 16 and then declined. These changes could have represented random variations and were considered unlikely to confound interpretation of any intervention effect. As this identification was retrospective, it is possible that other events exerting significant confounding effects were not detected.

In the absence of a control group the potential impact of trends in the management of hypertension in pregnancy elsewhere in the UK could not be excluded. Given growing concerns over litigation in antenatal care, it is possible that increased defensive medical practice could have contributed to a rise (or fall) in the proportion of women managed appropriately. Any such trends could still have been detected during the pre-intervention period but not if they occurred afterwards.

The intervention was unlikely to affect data collection. Case identification and data collection were retrospective. Therefore the intervention is unlikely to have affected data collection. It is possible that documentation in case records improved following the intervention although no improvements were detected refecting this. Such a change would have represented a benefit from the intervention.

The primary outcomes were assessed blindly or were measured objectively. Data collection for the case note review was not blinded but the outcomes comprised objective processes of care. The detection of key clinical events or processes in the case notes might have varied according to the vigilance of data collectors. Therefore, data collectors' awareness of the hypothesis that clinical care was expected to improve following dissemination of the guideline could have contributed to bias. However, given the complexity of interpreting such data in the assessment of compliance, any such effects are unlikely.

The primary outcomes were reliable or were measured objectively. As discussed above, the outcomes comprised objective processes of care. Two problems were encountered in relation to data collection. Firstly, clinical events and findings may have been inadequately documented in case notes. For example, it is possible that women did receive appropriate investigations but these were not documented or results were not adequately filed. However, given the importance of sufficient documentation for both communication and medico-legal purposes, it was appropriate to rely upon the presence of these data. The residual weakness lies in the possibility that a proportion of clinical encounters in the community were not recorded or filed in the completed case notes. Secondly, to meet with the requirement from ethical committees that only locally employed NHS staff had access to case records, several data collectors were used. It is possible that inter-observer variation significantly contributed to random error despite attempts to minimise this by using objective outcome measures, and by training and offering continual support to local data collectors.

A major problem concerned the measurement of compliance with the guideline recommendations. It was not feasible to measure every aspect of care that potentially contributed to the measurement of compliance. For example, much of the assessment of clinical management was confined to the seven days following the initial detection of raised DBP or proteinuria. In effect, the study used 'markers' or proxy measures of compliance. This was justifiable given that the study aimed to measure professional behavioural change provided that these measures were of sufficient sensitivity (see section 5.5.3).

The composition of the dataset at each time point covered at least 80% of the total number of participants in the study. All sampled cases were included in the analysis of the appropriateness of initial investigation. The analysis assessing the appropriateness of subsequent clinical management included over 85% of the sample. The appropriateness of clinical management for the remainder could not be judged given the lack of reliable diagnostic information. There was no indication of any trend in the proportion of such cases missing at each time point that would suggest case ascertainment bias.

The shape of the intervention effect was pre-specified. No data were collected over the intervention period. Therefore, if the intervention had any effect, only an upward shift in the intercept was expected.

A rationale for the number and spacing of data points was described. These were determined largely on pragmatic grounds. Twenty-four monthly (2 years) pre-intervention data sampling points were considered necessary to judge any preceding trends or seasonality in clinical

management. By considering 24 months, each calendar month was studied twice, thereby allowing seasonal effects to be investigated statistically. A further twelve monthly points were considered sufficient to assess post-intervention trends, including the decay of any intervention effect. It seemed implausible that dissemination and implementation of the guideline would have exerted a delayed effect 12 months or more post-intervention. Monthly data sampling points were judged sufficiently sensitive to identify important changes in practice. Weekly or daily data sampling points were avoided because they might have been associated with higher point-to-point variability.

The study was analysed appropriately using time series techniques. Logistic regression modelling, adjusted for the clustering per time point and hospital-level, was used. Although this method does not account for auto-correlation (i.e. compliance levels between any two time points may not be independent of one another), no evidence of auto-correlation was found when this was investigated using the autocorrelation and partial autocorrelation functions.

5.5.3 Explanation of findings

There are several possible causes for the failure to demonstrate any significant effect of the intervention: the study methods; the nature of the clinical guideline; and the effectiveness of the intervention.

The study methods. Four aspects of the study methods, in addition to those highlighted above (5.5.2), may account for the lack of effect.

Firstly, the outcome measures used may have been too insensitive to detect changes in practice. This concern arose when the outcome measures for appropriate clinical management were initially developed and tested. There were four broad criteria used to assess basic and enhanced surveillance: number of clinical contacts; in-patient admissions; investigations; and anti-hypertensive therapy. Compliance was zero if all four criteria were applied, thereby diminishing the ability of the time series to detect any changing trends. Therefore, 'relaxed' criteria were applied to increase the sensitivity of the outcomes to detect change. Even when overall compliance with appropriate management was 69.3%, no trends were detected. The lack of effect is unlikely to be attributable to the outcome measures employed.

The second issue concerns precision of the estimates of compliance. In planning the study, it was estimated that 40 cases per month would be sufficiently reliable. A mean of 35 cases per month were available for the measurement of initial investigation whilst a mean of 30 cases per month were available to measure the appropriateness of subsequent clinical management. Given the

wide error around each data point in the time series, this study lacked sufficient precision to detect any small to moderate changes in practice. Visual examination of the graph for appropriate initial investigation suggests a small increase in the intercept, raising the possibility that a small effect was not detected. However, there is little indication of any change in the intercept or gradient for subsequent clinical management, suggesting that a larger study sample would have been insufficient to detect a significant change.

The third issue concerns the number of data points. Following a non-significant post-intervention increase in the appropriateness of initial investigation, there was evidence of a 1.2% decay in compliance per month. Paradoxically, this decay could have caused an apparent intervention effect. Decreasing compliance in the last five to six data points contributed to the negative slope of the fitted line, hence increasing the level of effect at the intercept (start of the post-intervention period). Hypothetically, had compliance subsequently risen again the negative slope of the fitted line would have been reduced, thus diminishing the intervention effect. Similar effects occurred earlier in the series; compliance decreased over months 13-19 and increased over months 19-23. No statistical evidence was found of a seasonal pattern to explain these trends. Without further data points (beyond 12 months post-intervention) it is not possible to determine whether the increased post-intervention compliance for the appropriateness of initial investigation was artefactual or real.

The final possible explanation related to study methods concerns the gap of eight months in data collection between the pre- and post-intervention samples. This represented the intervention period. Had data been collected over this period, it may have demonstrated a temporary increase in compliance – related to raised awareness of the guideline. In planning this study, it was decided to focus the limited resources available for data collection so as to detect any secular and seasonal trends in the pre-intervention period and look for *sustainable* post-intervention effects. Although temporary effects are beneficial from both clinical and economic perspectives, the detection and monitoring of any more sustainable effects were given a higher priority.

The clinical guideline. The clinical guideline was introduced because of confusion amongst professionals over the different categories of hypertension in pregnancy and uncertainty as to what constituted optimal management. Whilst the guideline attempted to clarify these issues, the management of hypertension in pregnancy remains relatively complex. For example, women can move between different levels of care according to clinical findings and the results of investigations. This became notably apparent during the design of the data collection instruments and development and revisions of the outcome measures.

The hypertension guideline was published as one of a set of four obstetric guidelines. In the early stages of planning a time series analysis, it was intended to measure the impact of the guideline, *The Management of Pregnancy in Women with Epilepsy*. This plan was abandoned because of difficulty in obtaining relevant archive data (198). Clinician-reported practice assessed before and after dissemination of the epilepsy guideline suggested significant improvements in key aspects of care did occur (Chapter 4). Whilst self-reports over-estimate actual compliance (37;129) it is plausible that a time series, following an identical dissemination and implementation strategy, could have detected a significant change in practice in relation to the epilepsy guideline.

The intervention. Modest effects on care have been observed with the dissemination alone of educational materials (197). There is evidence that the passive dissemination of national guidelines can accelerate an existing trend in clinical practice if the overall context is hospitable, e.g. if clinicians or patients are receptive to change (199). Although the dissemination and implementation strategy for the hypertension guideline comprised other components, it was of a relatively low intensity – at least as far as local activities were concerned. Its effectiveness depended upon the actions of senior staff and existence of local mechanisms to promote implementation. It is debatable whether the strategy would have had a greater impact in the contemporary NHS given the advent of clinical governance and establishment of enhanced local mechanisms to promote clinical effectiveness (70).

A further limitation of the intervention concerned the range of professionals targeted. The guideline was intended for use by a range of professionals providing antenatal care, including community midwives and general practitioners. The latter provide the majority of antenatal care. However, the substantive part of the intervention targeted hospital obstetric and midwifery staff. A wider ranging or different type of intervention might have been more appropriate (and also more costly).

Despite some weaknesses in the study design, the most plausible explanations for the lack of effect by the guideline strategy are probably related to the nature of the guideline topic, the complexity of the guideline recommendations and the probable low intensity of local implementation activities.

5.5.4 Implications for practice and policy

The guideline was directly relevant to the 20.5% of women receiving antenatal care. Confusion over the optimal initial investigation and management of proteinuria and mild hypertension

remained following the dissemination of the clinical guideline. It was anticipated that evidence of inappropriate over-management would be found in women eligible for routine antenatal care. Less expected was the extent of insufficient monitoring of women eligible for basic or enhanced surveillance. However, anti-hypertensive treatment was initiated or withheld appropriately for the majority of women requiring enhanced surveillance.

The clinical impact of these shortcomings in the process of care depends upon the validity of the guideline recommendations. The guideline was developed in accordance with what was then accepted to represent a rigorous methodology (83). Certain recommendations, such as the avoidance of hospitalisation and the indications for anti-hypertensive therapy were allocated to grade A: requiring at least one randomised controlled trial as part of the body of literature of overall good quality and consistency (48). Yet little direct evidence of sufficient quality existed to support the use and content of different levels of surveillance advocated by the guideline. These recommendations were largely allocated as grade C: requiring evidence from expert committee reports or opinions and/or clinical experience of respected authorities. The lack of direct evidence presents a particular difficulty to health professionals who need to balance calls for lower thresholds of clinical suspicion (159) against others advocating less intrusive antenatal care (200). However, the type of focused, structured clinical care advocated by the guideline, and optimal risk management need not be mutually exclusive.

There is a case, based upon the experience of collecting data and measuring outcomes for this study, for re-appraising the recommendations within the guideline. This could address the content of recommendations (e.g. the necessity of checking urine specific gravity) or their presentation (e.g. the ease of following packages of care).

It would be premature to conclude that the method of disseminating and implementing guidelines studied here, nationally via a clinical effectiveness programme, is ineffective. Firstly, further evidence (e.g. from systematic reviews) is needed to judge the effects and consistency of such approaches across a range of contexts. Secondly, the relatively low costs of more passive methods of dissemination and implementation may justify their use, given the limited NHS resources available to support guideline implementation and uncertainty over what constitute the most effective strategies (197). Relatively modest effect sizes may still be sufficient to swing the cost-benefit ratio in favour of less intensive and expensive strategies.

5.5.5 Unanswered questions and research needs

Given the growing emphasis placed upon National Service Frameworks and clinical guidelines within the NHS, it is important to develop cost-effective means of their dissemination and

implementation (114). National managed clinical networks or programmes focusing on specific programmes (e.g. coronary heart disease, cancer) may provide the leadership and coordination necessary to support local implementation (201). Time series analyses represent an appropriate quasi-experimental method to evaluate the impact of these strategies, given the practical barriers to randomised evaluations in such circumstances. As well as evaluating the effectiveness of these strategies, further data are needed on their costs and on potential effect modifiers, such as the nature of the guideline recommendations (Chapter 2).

5.6 Conclusion

This interrupted time series analysis assessed the impact of the clinical guideline, *The Management of Mild, Non-proteinuric Hypertension in Pregnancy*. The intervention comprised distribution of the guideline under the auspices of SPCERH, supported by a national launch meeting and distribution of results of a pre-intervention audit of obstetricians' reported practice.

The appropriateness of antenatal care of 1263 pregnant women experiencing an episode of raised DBP, proteinuria or both was assessed. Care was consistent with the recommendations on initial investigation for 60% of women. Sufficient data were available on 1081 women to analyse subsequent clinical management, considered appropriate for 69%. Women eligible for routine care tended to be over-investigated or seen at clinics too frequently. Those with clinical problems requiring closer surveillance tended to be under-managed.

A time series analysis indicated a non-significant but temporary increase in the appropriateness of initial investigation after the intervention. No increase in the appropriateness of subsequent management was detected. The cost of guideline development accounted for 40% of the total costs whilst dissemination and implementation accounted for 60%. The mean cost of the dissemination and implementation activities was £1695 per obstetric unit in Scotland.

Despite some weaknesses in the study design, the most plausible explanations for the lack of effect by the guideline strategy were probably related to the nature of the guideline topic, the complexity of the guideline recommendations and the low intensity of local implementation activities.

Chapter 6

The identification of barriers to change and tailoring of a strategy to improve induced abortion care

6.1 Summary

Induced abortion is one of the most commonly performed gynaecological procedures. Major variations in the quality of care among gynaecology units have been demonstrated in Scotland. The Royal College of Obstetricians and Gynaecologists published the guideline, *The Care of Women Requesting Induced Abortion*, in March 2000. This chapter describes the development of a strategy to promote the implementation of this clinical guideline. Chapter 7 reports the cluster randomised controlled trial undertaken to evaluate of the effectiveness of this strategy.

Compliance with guideline recommendations was measured by a review of case notes. Barriers to and facilitators of guideline implementation were assessed as follows. Firstly, semi-structured interviews with local lead gynaecologists identified a range of factors reported to influence the implementation of five key guideline recommendations. Secondly, a survey, based upon constructs from the Theory of Planned Behaviour (TPB), measured the behavioural intentions, attitudes, subjective norms and perceived behavioural control (PBC) of staff providing abortion care. Two key recommendations were selected for this: offer of an assessment appointment within five days of referral; and supply of contraceptives at discharge if required. Correlations between the psychological measures and unit compliance were assessed. Thirdly, open-ended survey questions allowed staff to specify barriers.

Pre-intervention compliance data were available from 25 out of 26 gynaecology units for a total of 1073 patients. These data demonstrated variations among units and scope for improvements in care. A total of 507 case notes were reviewed for the 13 gynaecology units randomised to the trial intervention arm and hence eligible for the assessment of barriers. Median unit compliance was 46% for the assessment appointment and 59% for contraceptive supplies. Twelve units participated in the identification of barriers, with 151 out of 205 questionnaires returned completed (response rate 74%).

Lead gynaecologists reported the negative attitudes of staff in the wider organisation and limited resources as obstacles to offering an assessment appointment within five days of referral. According to the TPB survey, the mean behavioural intention of staff to follow this recommendation was already high. Mean PBC was lower. Subjective norm emerged as the best predictor of behavioural intentions (Adjusted R-squared = 0.27; p=0.001). Therefore, presenting

the offer of an assessment appointment within five days of referral as consistent with professional values and norms represented an appropriate approach to increasing behavioural intention. The TPB model best explained unit compliance when PBC was added to behavioural intention (Adjusted R-squared = 0.15; p=0.04).

Lead gynaecologists identified the availability and skills of clinical staff as important influences on the provision of contraception at discharge. Behavioural intentions to follow this recommendation were also high. PBC was the strongest predictor of behavioural intention (Adjusted R-squared 0.34; p=0.03). Therefore, the most appropriate interventions may have been those aimed at increasing PBC. The TPB model did not explain unit compliance.

This work informed the development of the strategy to promote guideline implementation. The strategy comprised a package, deliverable by a national clinical effectiveness programme, that included audit and feedback, educational meetings, the dissemination of a model structured case record, and the promotion of patient information. However, clinical staff were already highly motivated to implement the guideline recommendations but limited by organisational constraints. Interventions to promote the guideline need to target organisational barriers as well as individual professionals.

6.2 Introduction

6.2.1 Inappropriate variations in induced abortion care

Induced abortion is one of the most commonly performed gynaecological procedures, with over 12,000 annually in Scotland (202). Despite preventive measures, the number of abortions is rising, with women aged under-20 accounting for 24% of the total in 1998. The Gynaecology Audit Project in Scotland (GAPS) previously demonstrated major deficiencies in the quality of care among hospitals (203). For example, access to abortion services was inequitable, with barely half of women requesting abortion receiving an assessment appointment within five days of referral. The use of evidence-based interventions (e.g. screening for infections) to reduce the risk of complications was low. Despite improvements following the GAPS audit and feedback exercise, inappropriate variations in care persisted. Such variations became increasingly difficult to justify given an evolving evidence base and clinical governance. For example, in 1999 the proportion of abortions undertaken at less than 10 weeks gestation ranged across health boards from 76% down to 37% (202).

The Royal College of Obstetricians and Gynaecologists (RCOG) guideline, *The Care of Women Requesting Induced Abortion*, was published in March 2000 (51). It was developed in response to such concerns. The guideline promoted equitable access to services, the use of more effective interventions and improved communication with women. The guideline was developed by a multidisciplinary group according to rigorous criteria, including explicit methods of appraising and grading evidence (83). Recognising the importance of patient perspectives in judging the relevance of research, the Guideline Development Group included service user representatives from the Birth Control Trust and the RCOG Consumer Forum.

6.2.2 Selection of strategies to promote guideline implementation

The use of valid guidelines can improve clinical practice, especially if effective dissemination and implementation strategies are used (58). Yet systematic reviews indicate that few interventions to change professional and organisational practice work consistently across all circumstances (Chapter 1.4.2) (197). It has been suggested that implementation strategies should be based upon identified needs and barriers, allowing more rational selection or tailoring of interventions (55;100;145;170;204).

A systematic review of the effectiveness of continuing medical education found that 28 out of 160 comparisons evaluated targeted specific barriers or incorporated the use of a gap analysis technique (such as audits to determine sub-optimal performance) to tailor interventions (55). Such interventions were associated with higher rates of success. Although intuitively attractive,

there is little empirical evidence on the most appropriate methods of identifying needs and barriers (205) and the subsequent effectiveness of tailored strategies is uncertain (206).

6.2.3 Methods of identifying needs and barriers

It is often not known what factors are important in the relative success or failure of reported implementation strategies because of the lack of a common conceptual framework. Implementation studies require such a framework within which to describe common elements of settings, individuals, targeted behaviours, and interventions (207). Hence, it should be possible to identify what features influence the effectiveness of interventions. Various frameworks have been used to describe factors that may promote or hinder the implementation of guidelines, thus informing a 'diagnostic analysis' (15-18;39;100). In Chapter 1, barriers were considered (largely on pragmatic grounds) under the headings of the guideline recommendations, the characteristics of individual professionals, and the wider organisational context. A range of methods is available to identify such factors, including surveys, interviews, group interviews and direct observation. The combination of in-depth interviews with key informants to identify barriers and facilitators followed by large scale surveys to measure the extent of these factors amongst (say) clinical staff has been suggested as the most useful approach (205;208).

6.2.4 Identification of barriers within other intervention studies

A non-systematic sample of randomised trials of tailored interventions was identified from the reference list of a recent study of a tailored intervention (209). These six studies and the recent trial by Flottorp et al were appraised. Two of the seven studies provided no information on how barriers were identified (Table 6.1, possibly because of journal restrictions on word counts) (210;211). Methods described in other randomised evaluations include elucidation and discussion at focus groups (212), consensus meetings for local opinion leaders (213), small group educational meetings for targeted participants (214;215). Baker *et al* provide a more comprehensive account of the investigation of barriers (216). In-depth interviews with study participants were recorded and transcribed before analysis by researchers. The detail of descriptions given within individual studies is highly variable, thereby hindering interpretation and reproducibility.

Table 6.1 also summarises barriers identified in previous evaluations of tailored interventions. Identified barriers were not described in two reports (210;211). The other reports demonstrate the importance of organisational factors. The potential roles of individual clinician beliefs and attitudes is highlighted in three of the primary care studies, possibly because the guidelines focused on consulting skills and behaviours (212;215;216).

Table 6.1. Identification of barriers reported in seven studies of tailored interventions

Study	Guideline and setting	Method of identifying barriers	Reporting of barriers	Recommendation specific	Individual	Organisational or environmental	Intervention(s)
Santoso (212)	Appropriate drug use for diarrhoea in Indonesian primary care	Focus groups of clinicians and patients	Yes, limited		Conflicting clinician beliefs and perceptions	Conflicting patient beliefs and perceptions	Small group vs formal seminar
Soumerai et al (213)	Care for acute myocardial infarction in US secondary care	Consensus meetings of local opinion leaders	Yes, limited	Balancing benefits and harms of treatments		Need for updated protocols and policies	Educational outreach by local medical opinion leaders, audit and feedback, and revision of protocols
Cranney et al (214)	Management of hypertension in the elderly in UK primary care	Small group educational meetings	Yes			Time and workload pressures, absence of peer support or personal 'mentor', poor teamwork, inadequate computer system	Educational outreach
Van der Weijden et al (215)	Cholesterol control in Dutch primary care	Small group educational meetings	Yes, limited	Complexity of guideline	Lack of motivation	Time and workload pressures, lack of reimbursement, lack of practice organisation	Educational outreach, audit and feedback, and paper prompts
Hux et al (210)	Antibiotic use in Canadian primary care	Not stated	No				Educational materials, and audit and feedback
Baker et al (216)	Management of depression in UK primary care	In-depth interviews with clinicians	Yes		Conflicting beliefs, lack of preparedness to change, low self-efficacy	Lack of peer pressure or support, poor teamwork	Individually tailored combinations of educational outreach, audit and feedback, and small group discussion
Flottorp et al (209)	Management of urinary tract infections in women and sore throat in Norwegian primary care	Not stated	No				Patient educational material, computer based decision support and reminders, targeted reimbursement, and interactive education

6.2.5 Application of behavioural change theories

Theoretical models of change can be used to understand the behaviour of both health professionals and organisations (105;170). It is uncertain as to what degree previous intervention studies have explicitly and prospectively used behavioural change theory to assess barriers and tailor interventions. This question is currently being addressed by a systematic review (P Davies, personal communication).

Only one of the above studies explicitly drew upon behavioural theory to tailor the interventions (216). A selection of theories was used to interpret observed performance and interviews of general practitioners and guide the selection or tailoring of particular interventions. However, the validity of these theories in predicting or explaining behaviour was not tested.

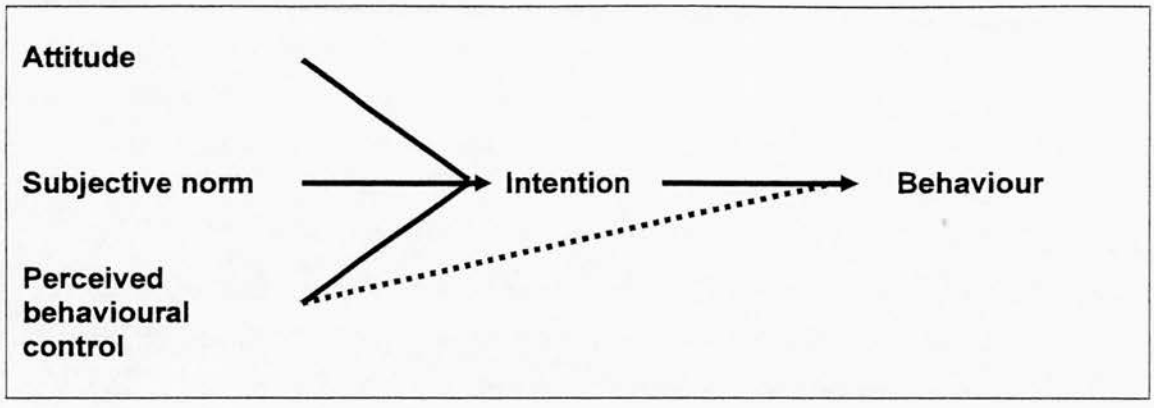
Elsewhere, a recent large-scale audit of compliance with evidence-based recommendations in obstetrics assessed factors, albeit mainly retrospectively, that influenced their implementation (217). Investigators interviewed managers and clinicians to measure to what degree they had moved along the continuum of the 'theory of implementation intentions' (218). This theory suggests that behaviour change is determined by the strength of intentions (or motivation) and to what degree steps have been taken to plan or implement change. Marked changes in practice were identified by the obstetric audit but these changes were not associated with the degree of planning reported by clinicians and managers.

6.2.6 The Theory of Planned Behaviour (TPB)

Motivational theories propose that motivation is a key determinant of behaviour, and therefore the best predictors of behaviour are factors that predict behavioural intention (or motivation). Motivational theories have been widely used in health promotion research to understand individual differences in health behaviours (e.g. exercise, condom use)(219). The theory of planned behaviour (TPB) is a motivational theory which proposes that individual behaviour is determined by intentions towards that behaviour (220) (Figure 6.1). The strength of a behavioural intention is determined by three variables:

- Attitudes towards the behaviour, arising from a combination of beliefs about its consequences and evaluations of those consequences
- Subjective norms based on the perceived views of other individuals or groups (i.e. perceived social pressure)
- Perceived behavioural control, encompassing beliefs about self-efficacy (the ability to perform an action) and wider environmental factors that facilitate or inhibit performance.

Figure 6.1. The Theory of Planned Behaviour (220).



Perceived behavioural control can also directly influence behaviour. The TPB model can be used both to explain or understand behaviour and to plan interventions to change behaviour. Interventions designed to strengthen or modify beliefs most strongly associated with behavioural intentions are expected to be the most effective in changing behaviour. In this way, TPB can inform the selection or tailoring of interventions to change clinical practice.

The application of TPB to understanding clinicians' adherence to evidence-based advice about their practice has been limited. However, early studies suggest that it is a useful, systematic tool to identify barriers to and facilitators of change and hence appropriate forms of intervention (221-224).

6.2.7 Scope of this Chapter

A strategy to promote implementation of the RCOG guideline, *The Care of Women Requesting Induced Abortion*, was developed and tested within a cluster randomised controlled trial: The Improving Abortion Care Trial (ImpACT). This chapter describes the combination of pragmatic and theoretically-based approaches used to identify factors that helped or hindered implementation of the guideline, and thereby inform the development of the ImpACT strategy. This process is set out largely in chronological order as follows:

- Early development of the strategy
- Measurement of pre-intervention compliance
- Methods used to identify potential barriers to and facilitators of implementation
- Factors identified as influencing compliance with the guideline
- Later development of the strategy
- Strengths and weaknesses of this work and implications for the implementation strategy

6.3 Methods

6.3.1 Context and early development of the strategy

This study took place within the intervention arm of ImpACT, fully described in Chapter 7. In brief, all RCOG fellows and members received identical printed guideline summaries. Half of the 26 gynaecology units in Scotland were randomised to the intervention whilst the other half acted as controls.

A *provisional* implementation strategy was developed for the original funding proposal to the Chief Scientist Office (CSO) (Table 6.2). The use of a multi-faceted strategy was favoured for two reasons. Firstly, available evidence then suggested that combinations of interventions were more effective than single interventions (102). Secondly, combining interventions would permit more than one barrier to be addressed (39;204). The content of the strategy was determined by what could feasibly be delivered under the auspices of a national clinical effectiveness programme (SPCERH). The methods of assessing factors that would influence guideline implementation were considered as potential co-interventions and limited to the intervention arm.

Table 6.2. *Provisionally* identified components of the intervention strategy.

Component	*Rationale*
Audit and feedback using pre-intervention data on performance at unit level	Demonstration of any differences between perceived and actual practice; stimulation of discussion as to what further barriers exist and means of overcoming them locally
Critical appraisal training focusing on evidence relating to induced abortion	Improved understanding of both the costs and benefits associated with the guideline recommendations (e.g. effectiveness and safety issues); development of generic skills in interpreting clinical evidence
Provision of structured case sheet for insertion into notes of women undergoing abortion	Reduction of errors of omission by maintaining awareness of guidelines at time of patient contact and prompting appropriate actions; detailing of more complex recommendations (e.g. drug regimens)

6.3.2 Pre-intervention compliance

A pre-intervention case note review was undertaken to assess compliance for three reasons. Firstly, it provided baseline data on performance for an audit and feedback component of the implementation strategy. Secondly, it provided measures of actual clinical behaviour to inform the analysis of the TPB survey. Thirdly, these data enabled randomisation of pairs of gynaecology units matched by pre-intervention performance. This third reason and the methods of the case note review are fully described in Chapter 7.

In brief, women undergoing induced abortion over a three month period were identified from ward admission books and fifty were randomly selected for a structured case note review to measure compliance with the RCOG guideline recommendations. All cases were reviewed in smaller units where 50 or fewer women underwent abortions during this period. Trained data collectors used a structured form to extract relevant clinical details. Data were entered onto an Access database (165) and analysed using SPSS (166).

6.3.3 Semi-structured interviews with lead gynaecologists

Semi-structured interviews were conducted with a lead gynaecologist in each intervention unit to identify barriers to and facilitators of implementing the induced abortion guideline. Clinical directors nominated the lead gynaecologists, usually selected because of their involvement in organising abortion care. A framework comprising factors related to the recommendations, to the health professionals and to the organisation was used, based upon an earlier literature review and experiences from SPCERH work (21).

Questions were based around the guideline recommendations selected as five key outcomes for ImpACT (see 7.3.6):

- Ideally, all women are offered an assessment appointment within five days of referral
- Assessment prior to induced abortion may be viewed as an opportunity to ascertain each woman's cervical cytology history
- Abortion care should encompass a strategy for minimising the risk of post abortion infective morbidity
- Misoprostol is a cost-effective alternative to gemeprost (early medical abortion, cervical priming, mid-trimester medical abortion)
- Contraceptive supplies should have been offered if required. The chosen method of contraception should be initiated immediately following abortion

A list of anticipated barriers and facilitators was drawn up for each recommendation, (illustrated for the offer of an assessment appointment in Table 6.3). All lead consultants were sent a letter, outlining the purpose of the interviews, what recommendations would be covered and general examples of factors that might influence adherence to guideline recommendations. Preliminary results of the pre-intervention case note review were fed back at the start of each interview. Interviewees were asked what factors they thought influenced compliance with each recommendation (see Appendix 6A for schedule). Otherwise, minimal prompting was used. The interviewer (RF) used a checklist of specific anticipated barriers and facilitators – not seen by the

interviewees - to minimise time spent writing notes. Following this, the planned trial interventions were outlined and the format and content of the educational meetings negotiated.

Table 6.3. Illustration of anticipated barriers and facilitators.

Offer of appointment with a gynaecologist within five days of referral	*Help implementation*	*Hinder implementation*
Recommendation-specific factors	Guideline produced by professional body (RCOG)	Lack of evidence supporting recommendation
Individual factors	Women seeking abortion seen as high priority	Women seeking abortion seen as low priority
Organisational or environmental factors	Existing telephone referral system	Delay mainly caused by referrer
	Unit guidance or targets available	Insufficient resources to improve referral system
	No limits on clinic appointments; or sufficient capacity	Coping with fluctuations in demand or supply

6.3.4 Development of TPB questionnaire

6.3.4.1 Questionnaire design and procedure

The questionnaire (Appendix 6B) focused on two of the five key guideline recommendations:

- Ideally, all women requesting abortion are offered an assessment appointment within five days of referral.
- Before she is discharged following abortion, contraceptive supplies should have been offered if required. The chosen method of contraception should be initiated immediately following abortion.

These recommendations were selected for two reasons. Firstly, the pre-intervention case note review indicated the existence of variations in care and potential for improved compliance. Secondly, individual professionals' control over following the recommendations was likely to differ, and was anticipated to be greater for the offer of contraception supplies at discharge.

The number of guideline recommendations assessed was restricted to two because the acceptability of the questionnaire to clinical staff was unknown. A draft questionnaire was produced. It was anticipated that the response rate would be enhanced if professionals understood the purpose and format of the questionnaire. Therefore, the questionnaire was preceded by a brief explanatory note and headings used throughout to guide respondents. More colloquial terms were used to describe psychological measures, i.e. 'motivation' was substituted

for 'behavioural intentions', 'social pressure' for 'subjective norms', and 'ability' for 'perceived behaviour control'. Wording of the items and the extreme labels were varied in direction to reduce the likelihood of response set. All of the items measuring psychological variables were rated on 7-point scales (1-7) with the extremes labelled according to the nature of each question. Measures of the TPB constructs used scales and items recommended by Ajzen (220) and Connor and Sparks (219).

It was recognised that staff had varying degrees of control over offering appointments or contraception and that these factors could influence how much control they had over following the recommendations. This was assessed by a closed question for each recommendation. The first asked whether a centralised referral service existed for abortions. The second asked who was responsible for providing contraception at discharge.

The draft questionnaire was piloted on three consultant gynaecologists, two specialist registrars and two staff nurses. These respondents answered six additional questions on the acceptability of the questionnaire. Following this, it became apparent that some respondents had become confused by the variation in direction of the extreme labels. The wording of the items and the extreme labels were varied less in the definitive version as some degree of response set was judged less detrimental to the interpretation of findings than confusion caused by varying the direction of the labels. Otherwise, the pre-tested respondents took 5 to 10 minutes to complete the questionnaire, and found it easy to understand, relatively easy to complete and acceptable. Some minor changes were made to the wording of items and the definitive questionnaire contained 30 questions.

6.3.4.2 Dependent variables

Behavioural intention. Intentions to follow the recommendations were measured by responses to a given scenario. For the first recommendation, it was: 'Next week, a woman is referred to your clinical teams by her GP requesting abortion'. Three items measured intentions: 'I intend to offer this woman an assessment appointment with five days of referral'; 'I want to offer this woman an assessment appointment with five days of referral'; and 'I plan to offer this woman an assessment appointment with five days of referral'. The response items consisted of 7-point scales labelled 'definitely do not – definitely do' with higher scores indicating stronger intentions.

For the second recommendation, the scenario was: 'Next week, a woman is being discharged from your unit following suction termination of pregnancy. She has indicated her wish to use the oral contraceptive pill but has not already been given supplies from any source.' The response stems and items were worded similarly to the first recommendation.

Behavioural intention was also analysed as an independent variable in the prediction of unit compliance.

Compliance with the recommendations. Data on individual professional performance were not available from the case note review. It was therefore planned to ask respondents about their own behaviour, e.g. how many women they had supplied contraception for in the preceding month. However, these questions were dropped following pre-testing as respondents found this difficult to estimate. Therefore unit compliance – as measured by the pre-intervention case note review – was used as a proxy measure for individual behaviour.

6.3.4.3 Independent variables

Attitude. Several of the beliefs underpinning attitudes towards both recommendations were identified during the course of the interviews with lead gynaecologists. For example, it was suggested that some professionals consider it is unfair that women requesting abortion should be managed as a priority over other patient groups. The mean of four bipolar items assessing attitudes towards the offer of an assessment appointment within five days was used as an attitude measure for this recommendation. The stem read, 'Overall, I think that offering this woman an assessment appointment within five days of referral would be...' The response items consisted of four 7-point scales labelled 'bad practice - good practice', 'harmful to her – beneficial to her', 'the wrong thing to do – the right thing to do', and 'unfair to women awaiting appointments for other reasons – fair'.

Similarly, the stem for the other recommendation read, 'Overall, I think that providing contraceptive supplies to this woman prior to discharge would be...' The response items consisted of four 7-point scales labelled as before except that the response on fairness was substituted by, 'a waste of time – a good use of time'.

Subjective norm. The mean of three bipolar items was used to assess subjective norms towards each recommendation. Different groups might be expected to approve or disapprove of following the recommendations. These were professional colleagues, professional bodies (the RCOG, the Royal College of Midwives, or the Royal College of Nursing) and other people important to the professionals. For each of these three groups, respondents rated 7-point items indicating the degree to which following the recommendation would be definitely approved or disapproved.

Perceived behavioural control (PBC). Five control items were included for each recommendation. Regarding the offer of an assessment appointment within 5 days of referral, high scores on a 7-point scale indicated stronger perceived behavioural control for four items. These comprised: offering this woman an assessment appointment is difficult / easy; the likelihood of being able to offer an appointment is very unlikely / very likely; confident in ability to offer assessment appointment (strongly disagree / strongly agree); and control over whether or not to offer appointment (no control / complete control). Lower scores indicated stronger control for the other item: factors outside control that prevent offer of appointment (strongly disagree / strongly agree). Regarding contraception at discharge, the items were worded and scored similarly except that lower scores also indicated stronger control for the item: control over whether or not to offer contraceptive supplies (complete control / no control). For questionnaire items where lower scores indicated stronger control, the scores were subsequently reversed on analysis.

6.3.4.4 Specific influences on behaviour

Brief open-ended questions asked what factors helped or hindered following the recommendations.

6.3.5 Survey sample and administration

The lead gynaecologists identified medical, midwifery and nursing staff involved in abortion care at their units. The questionnaires were posted to these staff along with a brief explanation about the purpose of the survey. A reminder was sent to non-responders three weeks later.

6.3.6 Analysis

Semi-structured interviews. Responses were collated and categorised under specific barriers and facilitators listed in the interview schedule. New barriers and facilitators were added as required.

TPB survey. Survey data were entered into an Access database (165) and analysed using SPSS (166). Summary measures for each of the four psychological variables (behavioural intention, attitude, subjective norm, and PBC) were calculated from the means of the contributing items. The correlations between behavioural intention and the other three psychological measures were analysed using Pearson's correlation coefficient.

The analysis accounted for clustering effects, whereby individual professionals within gynaecology units were more likely to respond in a similar manner. The intra-cluster correlation (ICC) measures the degree of this intra-cluster dependence (125). Failure to account for

clustering effects can lead to the over-estimation of the significance of results (152). Regression analysis using robust standard errors to adjust for clustering within hospital respondents was used to test for the strength of the relationship between behavioural intention, PBC and pre-intervention compliance. As there was some evidence of skewness in the responses to some behavioural measures, statistical analyses were repeated using non-parametric tests wherever possible.

An interim analysis was undertaken when 116 questionnaires had been returned. This was necessary if the TPB survey findings were to inform the later development of the intervention. This analysis differed from the final analysis (reported here) in two ways. Firstly, it did not account for clustering effects. Secondly, the interim analysis used categorical classifications of pre-intervention compliance to assess associations with the psychological variables. This approach substantially reduced statistical power to detect differences in levels of compliance.

In the analysis of the open-ended questions, more than one response was allowed for each respondent. A content analysis of factors that helped or hindered following the recommendations was undertaken (225). Two researchers (RF and GP) independently categorised the verbatim open-ended responses according to which component of a framework of barriers and facilitators they most closely fitted. The framework was piloted and modified. The final categories comprised: attitudes; subjective norms; and perceived behavioural control (self-efficacy, organisational and environmental). The responses were categorised blind to the gynaecology unit and grade of respondent, in case knowledge of these variables biased categorisation. A third researcher (AW) arbitrated where the first two disagreed over categorisations. Any disagreements were resolved by consensus.

6.4 Results

6.4.1 Pre-intervention case note review

6.4.1.1 Number of cases identified

A total of 1073 cases was identified by 25 units (Table 6.4). No cases were identified by Unit Z, based in a small, rural hospital. A total of 507 case notes (range 8 to 50) was reviewed for the 13 gynaecology units (A to M) randomly allocated to the intervention and hence to assessment of barriers to guideline implementation.

Table 6.4. Number of cases identified by each unit for pre-intervention case note review.

Unit	Number of cases identified
A	8
B	50
C	19
D	50
E	50
F	49
G	49
H	31
I	50
J	29
K	50
L	24
M	48
N	50
O	50
P	36
Q	47
R	50
S	50
T	50
U	36
V	48
W	50
X	49
Y	50
Z	0
Total	1073

6.4.1.2 Compliance with guideline recommendations

Tables 6.5 to 6.9 summarise the results of the pre-intervention case note review. These findings formed the basis of the baseline audit data fed back to the thirteen gynaecology units randomly allocated to the intervention arm. The baseline audit report presented detailed findings (appendix 6C). Brief commentaries on the findings for the primary outcome recommendations which were later discussed with the lead gynaecologists are included in section 6.4.2.2.

Table 6.5. Compliance with recommendations on organisation of services.

Organisation of services	Number of eligible cases	Number meeting criteria	Median compliance (%)	Inter-quartile range (%)
Ideally, all women are offered an assessment appointment within five days of referral (primary outcome)	1041	403	45.8	19.5, 53.1
As a minimum standard, all women are offered an assessment appointment within two weeks of referral	1041	924	91.8	78.9, 97.8
Ideally, all women can undergo the abortion within seven days of the decision to proceed being agreed	1054	889	87.5	76.3, 93.4
As a minimum standard, all women can undergo the abortion within two weeks of the decision to proceed being agreed	1054	1019	97.9	95.7, 100
As a minimum standard, no individual woman need wait longer than three weeks from her initial referral to the time of her abortion	1042	949	91.7	84.7, 97.0
In the absence of specific medical, social or geographical contra-indications, induced abortion may be managed on a day-case basis	1064	998	95.8	90.0, 100

Table 6.6. Compliance with recommendations on pre-abortion management.

Pre abortion management	Number of eligible cases	Number meeting criteria	Median compliance (%)	Inter-quartile range (%)
Pre-abortion assessment should include appropriate blood tests	1073	967	97.9	92.7, 100
It is not cost-effective routinely to cross-match women undergoing termination of pregnancy	1073	1064	100	98.0, 100
Assessment prior to induced abortion may be viewed as an opportunity to ascertain each woman's cervical cytology history (primary outcome)	776	413	57.9	20.2, 85.3
Women who have not had a smear within the interval recommended in their local programme may be offered a smear taken opportunistically	413	304	75.0	61.4, 85.1
Ultrasound scanning is not considered to be an essential prerequisite of abortion in all cases	1073	385	11.1	2.1, 76.5
Abortion care should encompass a strategy for minimising the risk of post abortion infective morbidity (primary outcome)	1073	1010	100	93.6, 100

Table 6.7. Compliance with recommendations on abortion procedures.

Abortion procedures	Number of eligible cases	Number meeting criteria	Median compliance (%)	Inter-quartile range (%)
Medical abortion is an appropriate method at gestations of <7 weeks / Conventional suction termination should be avoided at <7 weeks	132	111	89.2	45.8, 100
For early medical abortion, a dose of 200mg of mifepristone, in combination with a prostaglandin is adequate	354	324	100	100, 100
Use of conventional suction termination at gestations of 7-15 weeks if appropriate or preferred	918	587	62.5	42.5, 89.4
For women presenting between 7-15 weeks' gestation, suction termination may be safer under local anaesthesia than under general anaesthesia	587	2	0	
Misoprostol is a cost-effective alternative for gemeprost (early and mid-trimester medical abortion, and cervical priming; primary outcome)	1069	943	100	84.0, 100
Cervical preparation is beneficial prior to suction termination and should be routine if the woman is aged under 18 years or at a gestation of >10 weeks	164	158	100	100, 100
For mid-trimester medical abortion, a dose of 200mg of mifepristone is adequate	65	65	100	100, 100
Surgical evacuation of the uterus is not required routinely following mid-trimester medical abortion	65	62	100	100, 100
Mid-trimester abortion by dilatation & evacuation (D&E), preceded by cervical preparation, is safe and effective when undertaken by specialist practitioners*	0	0	0	
For women presenting at greater than 15 weeks' gestation, as an alternative to D & E, services may prefer to offer medical abortion	23	23	100	100, 100

*Denominator based upon surgical abortions.

Table 6.8. Compliance with recommendations on managing complications of abortion.

Managing complications of abortion	Number of eligible cases	Number meeting criteria	Median compliance (%)	Inter-quartile range (%)
Oxytocics are effective in reducing intra-operative blood loss	3	1		
In cases of suspected uterine perforation laparoscopy is the investigation of choice	2	2		

Table 6.9. Compliance with recommendations on after care.

After care	Number of eligible cases	Number meeting criteria	Median compliance (%)	Inter-quartile range (%)
Anti-D IgG should be given to all non-sensitised RhD negative women following abortion	194	182	100	89.4, 100
A follow-up appointment (either within the abortion service or with the referring clinician) within two weeks of the procedure should be offered to each patient following abortion	1073	255	10.2	2.5, 35.6
Before she is discharged following abortion, future contraception should have been discussed with each patient	1073	979	96.0	82.5, 100
Contraceptive supplies should have been offered if required. The chosen method of contraception should be initiated immediately following abortion (primary outcome)	1073	752	74.5	49.5, 90.8
Sterilisation can safely be performed at the time of induced abortion. However combined procedures are associated with higher rates of failure and of regret	1073	1057	100	97.0, 100
It is safe and effective to insert an IUCD for contraceptive use immediately following induced abortion	1073	117	8.0	4.0, 16.3

6.4.2 Semi-structured interviews with lead gynaecologists

6.4.2.1 Response rate

Twelve out of thirteen lead gynaecologists agreed to the semi-structured interviews. An interview could not be arranged with the thirteenth consultant (from unit C) within the available time frame. Consequently, no staff were identified from this unit for the staff survey.

6.4.2.2 Barriers and facilitators identified

The following issues were identified by lead gynaecologists as influencing compliance with each of five key recommendations (see Appendix 6D for detailed results).

Offer of an assessment appointment within five days. Median unit compliance with this recommendation was 45.8% [Interquartile range (IQR) 19.5-53.1%]. Median unit compliance in the intervention arm was 45.8% (IQR 19.3 - 56.9%). Most of the factors reported as influencing compliance with this recommendation were of an organisational nature. Factors that hindered implementation included problems coping with acute fluctuations in demand or supply (e.g. colleagues on leave, theatre list spaces, raised by 9 interviewees), more chronic shortages of space, facilities and staff (6) and insufficient resources to improve the referral system (3). In one

health board area served by unit D and two other units, there were historical problems in managing demand. Despite the existence of a centralised referral service, some GPs could get patients seen earlier if they by-passed this system. In other units, such as F, there was a reluctance to increase throughput within dedicated clinics because reduced appointment times might compromise proper counselling and other aspects of care.

Factors mentioned that facilitated implementation included the existence of a telephone referral system (raised by 9 interviewees), one person having responsibility for coordinating clinic appointments (5), and maintaining sufficient clinic capacity to manage fluctuations in demand (4). In two units, reminder letters were routinely sent to GPs who referred by letter rather than by telephone.

Individual factors also influenced service delivery. In six units, women seeking induced abortion care were seen as a high priority – usually by the lead consultant. However, five interviewees reported that other colleagues partially or not involved in providing abortion care assigned a lower priority to this client group compared with (say) women requiring investigation for potential malignancy. Three interviewees suggested that an increasing proportion of junior medical staff were opting out of providing abortion care, thus placing a greater amount of workload on the remainder.

Ascertainment of cervical cytology history. Median unit compliance was 57.9% (IQR 20.2 - 85.3%). More factors reported as influencing compliance centred around the recommendation itself. Doubts were expressed about the appropriateness of gynaecology units 'interfering' with a primary care-led screening programme (3), especially given the increased uptake of the programme in the community (2). However, two interviewees reported that a high priority was given to this aspect of care. Checking cervical smear status was easier to follow if it fitted in with routines, e.g. performing vaginal examinations in the clinic (2).

Individual factors appeared to act predominantly as barriers. Reasons suggested for low compliance included accidental omission from history taking (4) and failure to record history taking (4). Organisational factors mainly promoted adherence, especially where cervical cytology history taking was an established norm (4) or structured case notes were available (3).

Antibiotic prophylaxis or screening for lower genital tract organisms. Median unit compliance was 100% (IQR 93.6 - 100%). This recommendation had become the expected local norm in ten units, with seven leads reporting the availability of local guidelines or protocols. These organisational factors were supported by views about the recommendation itself, which was

perceived as being supported by convincing evidence (3), disseminated by credible bodies such as the RCOG or SIGN (3) and effective in reducing post-abortion complications (2) in a high risk population (2). A minority of colleagues was reported as having more negative attitudes because of concerns over acceptability of screening to patients (2) and disruption to routine care (2). One lead gynaecologist directly mentioned (and others alluded to) the increased costs associated with using more effective regimens.

Misoprostol as a cost-effective alternative to gemeprost. Median unit compliance was 100% (IQR 84 - 100%). This recommendation was widely supported by a range of recommendation-specific, individual and organisational factors. A convincing evidence base (4) was supported by a credible professional body, such as the RCOG (3). Using misoprostol offered distinct advantages over gemeprost, including fewer side-effects (3) and greater ease of storage (2). Cost-effectiveness was acknowledged as a priority by ten interviewees. The recommendation had often become an expected local norm (5), and was covered by local protocols or structured case sheets.

Four interviewees reported that several colleagues and pharmacists objected to the use of misoprostol tablets for abortion procedures by the vaginal route as this constitutes an unlicensed indication and an unlicensed route of administration. The guideline, however, states that the 'EC Pharmaceutical Directive 65/65/EEC specifically permits doctors to use licensed medicines for indications or in doses or by routes of administration outside the recommendations given in the licence.'(51) In unit G, the lead gynaecologist remained sceptical over purported benefits and planned to audit the introduction of misoprostol. Misoprostol was also unsuitable for cervical priming within the unit's 'fast track' abortion service.

Offer of contraceptive supplies if required at discharge. Median unit compliance was 74.5% (IQR 49.5 – 90.8%). Median unit compliance in the intervention arm was 58.6% (IQR 49.5 – 93.9%). Compliance was reported as being largely related to individual or organisational factors. Seven interviewees assigned a high priority to the provision of contraception at discharge. Whilst low compliance was sometimes explained by inconsistent recording in the case notes (3) or accidental omission (1), others saw provision as more of a priority for community services (1) or expressed uncertainty about the purported benefits of an active policy (1).

Organisational factors promoting the provision of contraception included the availability of a range of methods to offer women (7), its inclusion in unit guidelines or protocols (6), the availability of nursing staff trained in family planning (4), and a shared perception amongst staff that contraception was a priority (4). Good relations with or a close proximity to pharmacy

departments also helped (2). The absence of these factors reportedly had a detrimental effect, e.g. lack of choice of methods (4), shortages of appropriately trained staff (3), delays in obtaining supplies from pharmacies (2), or lack of a unit protocol (1). In unit E, there was an on-going dialogue with the pharmacy department over the legality of providing unlabelled supplies for storage on the ward.

6.4.3 Survey of clinical staff

Findings from the final analysis are presented below. Any major differences from the interim analysis are highlighted.

6.4.3.1 Response rate

Of 205 questionnaires sent, 116 (56%) questionnaires were returned in time for the interim analysis (Appendix 6E). Later, 151 (74%) had been returned for the definitive analysis (Tables 6.10 & 6.11). Two respondents had removed the gynaecology unit code from their questionnaires; their data could not be used in the subsequent analyses related to unit compliance. Response rates varied among grades of staff and disciplines, ranging from 100% for staff grade gynaecologists to 51% for senior house officers.

Table 6.10. Response rates to staff survey by discipline and grade.

Grade of recipient	Number of recipients	Number completing questionnaires*	Response rate (%)
Consultants	43	38	88
Staff Grades	5	5	100
Specialist Registrars	31	21	65
SHOs	45	23	51
Nursing and midwifery sisters	23	17	74
Staff midwives and nurses	58	43	74
Total	205	147	72

*Excludes four responses where grade unknown

Table 6.11. Response rates to staff survey by gynaecology unit.

Gynaecology unit	Number of recipients	Number completing questionnaires	Response rate (%)
A	6	6	100
B	18	16	89
C	-	-	-
D	15	12	80
E	8	8	89
F	31	25	81
G	22	14	64
H	14	11	79
I	14	11	79
J	18	12	67
K	23	14	56
L	8	4	50
M	28	16	60
Total	205	149	73

6.4.3.2 Reported organisation of services

Offer of an assessment appointment. Staff were asked whether patients were referred to their units via a centralised referral system. The presence or absence of such a system might influence their ability to offer an assessment appointment within five days. There was uncertainty about the existence of local referral systems in the majority of gynaecology units (Table 6.12).

Table 6.12. Staff awareness of a centralised referral system (n=144).

Gynaecology unit	*Patients referred via a centralised referral system*		
	No	Not sure	Yes
A	3	2	1
B	2	1	12
C	-	-	-
D	0	1	10
E	2	0	6
F	4	8	11
G	6	3	4
H	4	2	5
I	1	3	7
J	6	1	5
K	0	1	12
L	3	0	1
M	6	2	7
Not stated	0	0	2
Total	37	24	83
Total %	26	17	58

Provision of contraception. Similarly, staff were asked who usually provided contraception at discharge in their units. The responses to this question also varied among staff from the same hospital, suggesting confusion over responsibility for the provision of contraception (Table 6.13).

Table 6.13. Staff awareness of who usually provides contraception at discharge (n=144).

Gynaecology unit	Provision of contraception at discharge				
	Not sure	Contraception not routinely provided	Mainly medical staff	Mainly nursing staff	Combination of clinical staff
A	0	4	1	0	1
B	0	0	0	12	4
C	-	-	-	-	-
D	0	0	0	7	4
E	0	2	0	0	5
F	1	3	0	7	11
G	0	1	0	6	6
H	1	0	0	1	9
I	0	0	1	3	7
J	0	0	3	7	2
K	0	0	4	4	5
L	0	1	2	0	1
M	1	0	0	6	9
Not stated	0	0	0	0	2
Total	3	11	11	53	66
Total %	2	8	8	37	46

6.4.3.3 Pre-intervention compliance by unit

Pre-intervention data were used to measure compliance for the two key recommendations. Gynaecology units were initially divided into three groups: lower compliance within the lowest quartile; moderate compliance within the second or third quartile; and higher compliance within in the fourth quartile (Tables 6.14 & 6.15). Whilst this illustrates the spread of compliance among gynaecology units, there are problems with this categorical division of data. There is substantially reduced statistical power to detect differences across these groups and there is no evidence that there are three distinct groups, rather there is a continuum of compliance (i.e. it is a continuous measure)(226). The final analysis therefore evaluated the correlation between unit pre-intervention compliance and psychological variables.

Table 6.14. Pre-intervention unit compliance with assessment appointment within five days of referral.

Compliance	Units	Respondents
Lower (= or < 21%)	3	49
Moderate (21 – 53%)	6	64
Higher (>53%)	3	36

Table 6.15. Pre-intervention unit compliance with offer of contraceptive supplies at discharge.

Compliance	Units	Respondents
Lower (< 49%)	3	42
Moderate (49 – 94%)	6	76
Higher (>94%)	3	31

6.4.3.4 Psychological variables

Psychological variables. Scores on the four measures calculated for each of the two recommendations (behavioural intention; attitude; subjective norm; and PBC) are shown in Table 6.16. Respondent agreement with each of the four psychological variables was measured on a scale of 1 to 7. Higher scores indicate a stronger intention to perform the behaviour, a more positive attitude towards the behaviour, stronger subjective norm to perform the behaviour, and stronger perception of control over the behaviour. Six of these measures achieved acceptable internal reliability (Cronbach's alpha > 0.7). The two measures of subjective norm were relatively unreliable (assessment appointment alpha = 0.46, contraceptive provision alpha = 0.63).

Table 6.16 also illustrates a degree of skewness in the data. However, the results of the subsequent analyses were reproducible by non-parametric statistics with one exception (section 6.4.3.6).

Assessment appointment. The mean behavioural intention to comply with this recommendation was high. Mean perceived behavioural control was lower (3.95; SD 1.37). The ICC of 0.29 for perceived behavioural control was high, suggesting that staff within the same gynaecology unit were more likely to have similar levels of perceived control. The ICCs for the other variables were much smaller, suggesting that responses to behavioural intentions, attitude and subjective norms were more related to individual staff rather than a 'unit' effect.

Contraceptive supplies. The mean behavioural intention to comply with this recommendation was high. However, mean perceived behavioural control was higher (6.03, SD 1.13) compared with that for the offer of an assessment appointment. The ICCs followed a broadly similar pattern to the first recommendation, suggesting a common effect of gynaecology units on perceived behavioural control.

Table 6.16. Psychological measures on assessment of appointment within five days of referral and offer of contraceptive supplies at discharge.

	Mean	SD	Median	ICC
Assessment appointment				
Behavioural intentions	6.16	1.12	6.67	0.0007
Attitude	6.37	0.99	7.00	0.098
Subjective norms	5.93	0.89	6.00	0
PBC	3.95	1.37	4.00	0.29
Contraceptive supplies				
Behavioural intentions	6.69	0.87	7.00	0.048
Attitude	6.78	0.72	7.00	0
Subjective norms	6.49	0.67	6.67	0.075
PBC	6.03	1.17	6.60	0.22

6.4.3.5 Prediction of behavioural intention

Relationships between behavioural intention and the other psychological variables were examined for each recommendation.

Assessment appointment. All psychological variables were significantly correlated with one another (Table 6.17). After regression adjusting for the clustering in the data, subjective norm emerged as the best predictor of intentions to offer an assessment appointment within 5 days (attitude Beta =0.05, p=0.58; subjective norm Beta =0.52, p=0.001; and PBC Beta =0.13, p=0.10). Overall, the TPB measures accounted for 27% of the variance in behavioural intention (Adjusted R-squared = 0.27; p=0.001).

Contraceptive supplies. All psychological variables were also significantly correlated with one another (Table 6.17). In the interim analysis, attitude appeared to be the measure most highly correlated with behavioural intention. Following the final regression analysis, PBC was the strongest predictor of behavioural intention (attitude Beta =0.37, p=0.27; subjective norm Beta =0.37, p=0.16; and PBC Beta =0.15, p=0.03). Overall, the TPB measures accounted for 34% of the variance in behavioural intention (Adjusted R-squared 0.34; p=0.034).

Table 6.17. Correlations (Pearson's r) among psychological variables.

	Behavioural intentions	Attitude	Subjective norms
Assessment appointment			
Behavioural intentions	-		
Attitude	0.31**	-	
Subjective norms	0.51**	0.44**	-
PBC	0.29**	0.19*	0.28**
Contraceptive supplies			
Behavioural intentions	-		
Attitude	0.45**	-	
Subjective norms	0.50**	0.49**	-
PBC	0.32**	0.07*	0.37**

*Correlation significant at the 0.05 level (2-tailed).
**Correlation significant at the 0.01 level (2-tailed).

6.4.3.6 Psychological measures and prediction of pre-intervention compliance

Scores on questionnaire measures were compared across the unit levels of compliance for both recommendations.

Assessment appointment. Attitudes and perceived behavioural control were positively and significantly associated with unit pre-intervention compliance ($p=0.03$ and $p<0.001$ respectively, Table 6.18). The non-significant correlation between pre-intervention unit compliance and behavioural intentions ($p=0.06$) suggested that higher behavioural intentions were associated with working in higher complying units. Both the interim analysis and non-parametric testing did not detect a significant association.

On regression analysis, behavioural intention alone significantly predicted unit compliance (Adjusted R-squared = 0.04; $p=0.008$). The predictive power of the model increased when PBC was added to behavioural intention (Adjusted R-squared change = 0.11; $p=0.04$).

Contraceptive supplies. Both subjective norms and perceived control were positively and significantly associated with unit pre-intervention compliance ($p=0.04$ and $p<0.001$ respectively, Table 6.18). On regression analysis, there was no evidence that behavioural intention predicted unit compliance with the offer of contraception at discharge (Adjusted R-squared = 0.004; $p=0.48$). The addition of PBC had no statistically significant impact (Adjusted R-squared change = 0.10; $p=0.16$).

Table 6.18. Correlation between psychological variables and unit compliance for assessment appointment within five days of referral and contraceptive supplies at discharge.

	Correlation with pre-intervention compliance	P value
Assessment appointment		
Behavioural intentions	0.165	0.06
Attitude	0.186	0.03*
Subjective norms	0.158	0.07
PBC	0.371	<0.001
Contraceptive supplies		
Behavioural intentions	0.053	0.52
Attitude	0.003	0.97
Subjective norms	0.178	0.04
PBC	0.306	<0.001

*Non-significant on non-parametric testing

6.4.3.7 Barriers and facilitators identified by respondents

Assessment appointment. One hundred and thirty-eight open-ended responses were categorised regarding the offer of an assessment appointment (Table 6.19). For these 138 comments, RF and GP initially agreed on 129 (93%) categorisations. All remaining disagreements were resolved by consensus. The majority of responses (126, 91%) related to perceived behavioural control. Out of these, most factors perceived to help or hinder implementation were of an organisational nature. Overall, respondents reported more factors that acted as barriers than as facilitators.

Contraceptive supplies. One hundred and twenty-five open-ended responses were categorised regarding the offer of contraception at discharge (Table 6.19). For these 125 comments, RF and GP initially agreed on 96 (76%) categorisations. All remaining disagreements were resolved by consensus. Once again, the majority of comments (114, 91%) concerned perceived behavioural control, and specifically organisational factors. However, environmental factors (such as patient characteristics) accounted for a greater proportion of reported barriers (20, 28%). Factors reported as barriers and those as facilitators were more evenly divided.

Table 6.19. Factors reported as helping or hindering following the guideline recommendations.

	Assessment appointment within 5 days				Contraceptive supplies at discharge			
	Example of response (respondent number)	Helped (%)	Hindered (%)	Total (%)	Example of response (number)	Helped (%)	Hindered (%)	Total (%)
Attitudes including outcome beliefs, i.e. perceived benefits from following recommendation	Some delay is surely needed to prevent precipitate decision-taking by a woman who has not come to terms with the problem (046)	5 (14)	3 (3)	8(6)	Opportunistic! Good chance to educate and give sound relevant advice and provide method (011)	4 (7)	4 (6)	8 (6)
Subjective norms i.e. impact of colleagues and professional bodies	(Difficulty is) finding agreement with other colleagues (111)	1 (3)	3 (3)	4 (3)	Not everyone committed (043)	2 (4)	1 (1)	3 (2)
Perceived Behavioural Control (PBC; three sub-categories)		31 (84)	95 (94)	126 (91)		48 (89)	66 (93)	114 (91)
Self-efficacy i.e. the individual's skills and abilities	Its' my clinic. Therefore I can add urgent patients if I wish (003)	1 (3)	22 (22)	23 (17)	Not having personal experience or formal training in family planning (087)	5 (9)	8 (11)	13 (10)
Organisational e.g. availability of time & resources	System works well and efficiently unless colleagues are on leave when less appointments are available (021)	28 (76)	73 (72)	101 (73)	(Those women requiring) unusual oral contraceptive or implant need referral (017)	42 (78)	38 (54)	80 (64)
Environmental e.g. patient needs and demands	(Made easy by) gestation of pregnancy. Higher gestations will be seen quicker as a priority (066)	2 (5)	0 (0)	2 (1)	Women may deny need for contraception (002)	1 (2)	20 (28)	21 (17)
Total responses		37	101	138		54	71	125

6.5 Later development of the strategy

6.5.1 The process of linking barriers to strategy development

The strategy to promote implementation of the guideline was further developed following analysis of pre-intervention compliance, semi-structured interviews with the lead gynaecologists and the interim analysis of TPB questions from the staff survey. Information from these three components contributed to tailoring of the intervention as follows:

- *Pre-intervention unit compliance:* demonstration of local scope for improvement; prioritisation of feedback to each gynaecology unit
- *Semi-structured interviews:* provision of information on what factors helped or hindered implementation of recommendations, including which barriers were specific to individual units or more generally related to each recommendation
- *TPB survey:* information on which individual factors were associated with compliance and might be amenable to change

Pre-intervention unit compliance was presented to and discussed at a meeting of the ImpACT Steering Group (Appendix 7A). Interpretation of the interim TPB analysis was undertaken in conjunction with the behavioural scientist (AW). Summaries of the semi-structured interviews and the TPB analysis were discussed with other members of the Steering Group. The content of the implementation strategy was subsequently modified. It is worth noting that most of these discussions were relatively informal and took place within the short time available (two weeks) between the analysis of data on barriers and the first gynaecology unit outreach meeting. Therefore, the scope for both reflecting on the overall findings and systematically linking them to the content of the strategy were limited.

The final, multi-faceted strategy was intended to represent a range of activities that could feasibly be carried out by a clinical effectiveness programme. Table 6.20 summarises the content of each intervention component and the rationale for its inclusion.

Table 6.20. Summary of interventions used and rationale.

Intervention	Refinements made in later development	Rationale
Audit and feedback	Feedback to each unit focused on five main outcome recommendations and those where local compliance was in the lowest and highest quartiles	Represents an intervention frequently used by SPCERH Local strengths and weaknesses highlighted by selective feedback
Educational meetings	Most units opted for a one hour meeting rather than a half-day workshop Key messages refined in light of preliminary analysis of TPB survey	Shorter meetings more compatible with postgraduate programmes Discussion of local barriers and potential solutions encouraged by interactive approach
Review of structured case records	Illustrative structured case record disseminated Copies were not printed for inclusion in local unit notes	Potential of prompts and reminders to reduce errors of omission Structured case records already used by majority of units Local amendments to existing records considered more acceptable and feasible
Promotion of patient information booklet	RCOG booklet, downloadable from website, became available during development of strategy	Units able to amend or add local patient information Potential of changed patient expectations to influence subsequent provision of care

6.5.2 Audit and feedback

Audit and feedback comprises any summary of clinical performance fed back to health professionals (155). Within ImpACT, this intervention was designed to demonstrate differences between perceived and actual practice, thereby highlighting poorer than expected compliance with the guideline, or reinforce good performance (227). Presenting performance data from all gynaecology units in Scotland made indirect use of peer pressure.

All lead gynaecologists were sent several copies of a feedback report for circulation to relevant clinical staff within each intervention unit (Appendix 6C). Data from the pre-intervention case note review, measuring compliance with each of 27 guideline recommendations, was used in the compilation of audit results for each unit. For each recommendation, the feedback document presented:

- Grade of recommendation

- Rationale or supporting evidence
- How the case note data were analysed to measure compliance
- The total number of cases assessed for each recommendation
- Bar charts detailing median compliance with the upper and lower quartiles
- A brief commentary on the findings, including comments from lead gynaecologists on factors that helped or hindered implementation

The report emphasised the limitations of the audit data. Firstly, the sample size of up to fifty cases per unit was relatively small and therefore some of the variation among units may have been caused by random variation. Secondly, case note reviews underestimate actual compliance with guideline recommendations when patients *receive* care which is not *recorded* in the case notes. However, clear recording in case notes was important for the majority of the recommendations, least of all for medico-legal purposes. Feedback was anonymised so that gynaecology units on the bar charts were only identifiable by an alphabetical letter sent out with each report. The feedback documents were sent out as soon as possible following data analysis to be available before the next stage of the intervention package.

6.5.3 Educational meetings

Educational outreach visits entail the use of a trained person who meets with professionals in their practice settings to provide information with the intent of changing their performance (228). The information given can include feedback on performance. Within ImpACT, educational meetings were intended to provide convincing evidence or reasons to justify changes in practice where guideline recommendations were not being followed.

The meetings took place at gynaecology units over May and June 2001 (with one taking place later in July). Each unit was offered the option of a one hour educational meeting (largely to fit in with existing continuing medical education programmes) or a longer three hour workshop. Twelve units opted for the short meeting and one for a two hour meeting (unit B).

Each meeting contained the following components (presented by RF):

- A *brief* outline of the IMPACT study
- Background to the RCOG guideline
- Feedback of baseline audit results – focusing on five key recommendations and those recommendations where local unit compliance was in the lowest and highest quartiles
- The rationale for and evidence supporting key recommendations

- Feedback of barriers identified from the staff survey and interviews with lead gynaecologists
- Discussion of barriers and potential solutions

All meetings were accredited for continuing medical education. All staff involved in the provision of abortion care, including nursing and clerical staff, were encouraged to attend. Immediately following each meeting, a shorter meeting took place with lead consultants and other key individuals to formulate a local action plan. Two days later, the lead gynaecologists were sent a follow-up letter summarising the main action points agreed.

6.5.4 Review of structured case records

Structured case records act as prompts or reminders, prompting health professionals to perform a patient specific clinical action (229;230). Discussions with gynaecologists highlighted the potential benefits of structured records in reducing errors of omission (e.g. checking cervical smear status) or detailing more complex recommendations (e.g. drug regimens).

The original application to the CSO suggested the use of structured case records to help improve care. When contacted later, the majority of units (at least fourteen) reported that they already used structured case records. There were variations in the content of these case records, especially regarding follow up arrangements and contraception. Therefore, copies were obtained of all structured case records in use across Scotland. These were reviewed and a suggested 'model' case record was developed and finalised after pre-testing on a small convenience sample of gynaecologists and nurses. Paper and electronic format copies of the model case record were circulated to all intervention units (Appendix 6F). This package included a structured discharge letter modified from a version already used by one unit.

6.5.5 Promotion of patient information booklet

Patient mediated interventions comprise any intervention aimed at changing the performance of health professionals where specific information was sought from or given to a patient (231). In 2001, the RCOG published an information booklet for women having an induced abortion. The booklet was available as a downloadable A4 version via the College website. The content and availability of this booklet were highlighted to intervention units. It was suggested that the booklet, or a local modification of it, could be distributed to women attending clinics.

6.5.6 Tailoring of educational messages

Educational messages for two key recommendations presented at meetings were refined in light of findings from the interim analysis of the TPB survey. As all of the points raised at each

meeting could not then be dealt with in detail, a summary of responses to 'Frequently Asked Questions' (FAQs) was circulated to all intervention units four to six weeks after each meeting (Appendix 6G). This sheet included a summary of what action other gynaecology units had taken to improve implementation of key recommendations.

For the offer of an assessment appointment within five days of referral, behavioural intention was most strongly associated with subjective norms. Meeting this recommendation was presented as the professional norm. In an earlier survey, 81% of Scottish gynaecologists agreed or strongly agreed that 'referral to appointment' interval should be five days or less (232). In addition to this, the FAQ sheet highlighted other potential benefits of offering assessment appointments earlier. For example, the earlier in pregnancy an abortion is performed, the lower the risk of complications (233;234).

For the offer of contraceptive supplies at discharge, behavioural intention was most strongly correlated with attitudes – according to the interim analysis. The educational message regarding this recommendation therefore focused on changing outcome beliefs, i.e. the benefits of ensuring women had received contraceptive supplies by discharge were discussed. The FAQ sheet provided a worked example. This suggested that if in an average sized gynaecology unit an additional 10-20% of women were prescribed contraception immediately following abortion, between 5 and 25 unwanted pregnancies could be prevented in the following year. Across Scotland, this would translate into the prevention of between 120 and 600 unwanted pregnancies. Hence, considered in the context of other 'numbers needed to treat' (e.g. use of antenatal steroids)(3), provision of contraception at discharge could be relatively effective.

6.6 Discussion

6.6.1 Main findings

A multi-faceted strategy, based upon what could be delivered within a national clinical effectiveness programme, was developed to promote the implementation of the induced abortion guideline. The baseline (pre-intervention) audit indicated variations in compliance with guideline recommendations across recommendations and among gynaecology units. Barriers and facilitators were assessed systematically among gynaecology units in the intervention arm of the trial by three methods. Semi-structured interviews with local lead gynaecologists identified a range of barriers to the implementation of five key recommendations. The postal survey of clinical staff assessed behavioural intentions and beliefs in relation to two of these recommendations: assessment appointment within five days of referral; and provision of

contraception at discharge. This information was complemented by open-ended responses to the staff survey.

In the intervention arm, less than half of all women (46%) referred for induced abortion care were offered an assessment appointment with five days. Limited resources and underlying attitudes of staff in the wider organisation were reported as major barriers to the implementation of this recommendation. There was uncertainty among individual staff about the existence of local referral systems in most gynaecology units. Staff generally had strong behavioural intentions to offer an assessment appointment within five days but perceived control over this action was low. As subjective norm explained 27% of behavioural intention, it was considered appropriate to tailor educational messages to suggest that this recommendation was consistent with professional norms and values. Behavioural intention alone explained 4% of unit compliance compared to 15% when PBC was also considered. In other words, compliance was higher in units where staff believed they had more influence over the offer of an assessment appointment.

In the intervention arm, 59% of women received contraceptive supplies, as required, at discharge. The availability and skills of clinical staff were reported as the most important barriers. In addition, there was some confusion in several units as to who was responsible for the provision of contraception at discharge. Staff expressed strong behavioural intentions to offer contraception at discharge, with PBC explaining 34% of intention. Therefore, actions that could increase perceived behavioural control represented the most appropriate intervention. However, it appears that staff experienced substantial problems in putting these intentions into practice as the TPB model did not explain variation in unit compliance.

The final strategy consisted of audit and feedback, outreach educational meetings, dissemination of a model structured case record and promotion of patient information. The format of the interventions was negotiated with local lead gynaecologists and the educational content refined according to identified barriers and predictors of behavioural intention.

6.6.2 Comparison of methods used to identify barriers and facilitators

The main findings from the interviews with lead gynaecologists, and the TPB and open-ended questions from the staff survey were compared (Tables 6.21 & 6.22). These comparisons give some indication of the ability of the various methods to identify barriers and facilitators but should be interpreted with caution. Firstly, the semi-structured interviews and open-ended questions identified factors perceived by respondents to influence compliance whereas the TPB questions identified factors associated with actual compliance (using unit performance as a

marker for individual practice). Secondly, the method used to compare findings draws upon the categorisation system used for the analysis of open-ended questions. As such, factors identified in the semi-structured interviews were re-assigned to these categories *post-hoc*, e.g. recommendation-specific factors were considered under attitudes whilst individual factors were usually placed within attitudes, subjective norms or self-efficacy. For example, the need for family planning training of nursing staff to enable improved provision of contraception at discharge was categorised under self-efficacy (as a belief contributing to PBC, section 6.2.6) although it is also an organisational issue. Insufficient data were available from the TPB analysis to permit a further sub-categorisation of PBC into self-efficacy, organisational and environmental factors. Thirdly, the impact of each factor has been judged qualitatively as low, moderate or high.

Table 6.21. Comparison of findings from different methods used to identify factors that influenced the offer of an assessment appointment within five days.

Factors influencing compliance with recommendation	*Method of identifying barriers and facilitators*		
	Semi-structured interviews with lead gynaecologists (n=12)	Theory of Planned Behaviour survey questions (n=144)	Open-ended survey questions (n=144)
Attitudes	Moderate	Moderate	Low
Subjective norms	Low	Low	Low
Perceived behavioural control	High	High	High
Self-efficacy	Low	n/a	Moderate
Organisational	High	n/a	High
Environmental	Moderate	n/a	Low

Assessment appointment. All three methods identified perceived behavioural control as having a major influence on the ability to follow this recommendation. Findings from the semi-structured interviews and open-ended questions suggested that specific organisational factors represented the predominant influence. However, the open-ended questions from the staff questionnaire appeared to be less sensitive in identifying attitudinal factors, possibly because the respondents were reluctant to report negative attitudes.

Table 6.22. Comparison of findings from different methods used to identify factors that influenced the offer of contraception at discharge.

Factors influencing compliance with recommendation	*Method of identifying barriers and facilitators*		
	Semi-structured interviews with lead gynaecologists (n=12)	Theory of Planned Behaviour survey questions (n=144)	Open-ended survey questions (n=144)
Attitudes	Low	Low	Low
Subjective norms	Low	Moderate	Low
Perceived behavioural control	High	High	High
Self-efficacy	Moderate	n/a	Moderate
Organisational	High	n/a	High
Environmental	Moderate	n/a	Moderate

Contraceptive supplies. Once more, all three methods identified PBC as a major influence on compliance. However, PBC added to behavioural intention did not significantly explain compliance following regression analysis. The semi-structured interviews and open-ended questions specified the effects of organisational factors and further suggested that both self-efficacy and environmental factors exerted moderate influences on practice. Environmental factors included the refusal of some women to accept contraception at discharge.

The findings from the three approaches need to be considered within their specific contexts. The staff survey mainly comprised members of staff providing abortion care. Behavioural intentions and positive attitudes towards abortion care were already high in this group of staff – and therefore these factors did not represent barriers. However, the interviews with lead gynaecologists suggested that attitudes to abortion care among other colleagues or in the wider organisation were less supportive.

6.6.3 Strengths and weaknesses of methods used to identify barriers and facilitators

Pragmatic and theory-based approaches were combined to identify local needs and barriers to implementation of the guideline. The systematic approach increased the likelihood of identifying most factors that significantly influenced adherence to the guideline.

The use of a behavioural theory (TPB) offered three advantages. Firstly, it contributed to the diagnostic analysis by measuring the extent of potentially remediable factors, such as beliefs and intentions. This diagnosis informed the development of an implementation strategy. Secondly, the use of theory enhances the transferability of findings from intervention studies. It is often not

known what factors are important in the relative success or failure of reported strategies because of the lack of an established conceptual framework. Thirdly, psychometric methods may be more valid and reliable in the identification of individually-mediated barriers and facilitators. Many studies have investigated why clinicians follow clinical guidelines or not (212-216). Most of these studies describe clinicians' reported *reasons* for their actions but these reasons are not necessarily the same as the *causes* of their behaviour. A sceptical view is that reasons such as organisational constraints are actually rationalisations of negative individual attitudes to changing practice. However, the use of TPB in this case provided empirical evidence that highly motivated individuals were constrained by organisational factors.

The major limitation is that TPB did not represent the most appropriate approach to identifying wider factors that influence behaviour, such as the organisation and wider environment (235). The interviews with lead gynaecologists did provide such information. Yet this complementary approach was not based upon a theory-derived framework, thus limiting its transferability. Another limitation is that it was not possible to obtain data on the performance of individual professionals. Unit compliance was used as a proxy measure for individual behaviour. This might have compromised the ability to identify statistically significant relationships between individual intentions and behaviour.

Response bias represents a potential threat to external validity. The absence of any interview or questionnaire survey data from one gynaecology unit is noteworthy; this unit's levels of compliance with both guideline recommendations assessed by the TPB survey were in the lowest quartiles. Therefore, information about poorer performing units was lost.

The overall response rate from the other twelve units participating in the staff survey was satisfactory, notably with a high response rate from consultants (88%). The lower response rates from junior medical staff may have reflected greater mobility or perceived irrelevance of the survey. Whilst the survey responses are likely to be representative of staff directly involved in the provision of abortion care, the beliefs and intentions of staff in the wider organisation were not ascertained. Several lead gynaecologists suggested that other members of staff can have indirect but important influences on the provision of abortion care through, for example, competition for limited resources.

At a practical level, the process of identifying barriers was time-consuming both for the researchers and to a lesser degree for local clinical staff. This had consequences for the study itself and has implications for their more general application. Firstly, within the limited time frame of the research project, the intervals between identification of barriers, their analysis and

delivery of the intervention were both short. Indeed, these processes over-lapped to some degree. This allowed little opportunity to reflect on the findings and modify the interventions more systematically. The need to undertake an interim analysis of the TPB survey – initially ignoring clustering effects – led to the over-estimation of the influence of attitudes on individuals' intentions to offer contraception at discharge. Secondly, outwith research contexts, methods used to identify barriers can be prohibitively time-consuming and too complex to justify their routine use in the development of guideline implementation strategies.

6.6.4 Implications for the implementation strategy

The strategy to promote the guideline was tailored in the light of barriers and locally identified needs. The content and format of the strategy were negotiated with local lead gynaecologists. Low and high levels of compliance with recommendations relative to other gynaecology units were highlighted during feedback. The interactive nature of the educational meetings encouraged staff to link feedback on unit performance to their own experiences and identify ways of improving service delivery (15). The ImpACT strategy was relatively novel because its development was refined according to empirical data that attempted to explain behaviour. The educational messages subsequently targeted factors initially considered most strongly associated with intentions to follow two key recommendations.

Refinement of the strategy. Subjective norms best explained behavioural intentions to offer an assessment appointment. Therefore, this recommendation was presented as consistent with professional norms, albeit with some difficulty since the pre-intervention case note review clearly indicated it was not the norm throughout Scotland. However, participants in meetings were reminded that in response to an earlier survey, 81% of Scottish gynaecologists agreed or strongly agreed that 'referral to appointment' interval should be five days or less (232). On later reflection, there were three limitations to this approach. Firstly, the measure of subjective norm was unreliable (Cronbach's alpha = 0.46). A subsequent sub-analysis indicated that subjective norm item, 'Most professional colleagues would offer this woman an assessment appointment within five days of referral' was the best predictor of behavioural intention (Beta=0.16, p=0.05). Secondly, the mean behavioural intention of staff involved in the provision of abortion care to follow this recommendation was already generally high. Any interventions that aim to improve performance by increasing behavioural intentions alone were likely to encounter 'ceiling effects' or even become counter-productive. Thirdly, PBC was the strongest predictor of unit compliance. Reconfiguring appointment systems to improve their reliability and give professionals greater control over the offer of assessment appointments may have represented a more appropriate approach to improving compliance.

Lead gynaecologists reported the negative attitudes of staff in the wider organisation and limited resources as major obstacles to offering an assessment appointment within five days of referral. Therefore, interventions targeting both the attitudes and beliefs of those with greater power and the wider organisation may have been more promising.

For the offer of contraceptive supplies, behavioural intention was most strongly correlated with attitudes – according to the interim analysis. The educational message regarding this recommendation therefore focused on changing outcome beliefs, i.e. the benefits of ensuring women had received contraceptive supplies by discharge were discussed. The final analysis indicated that PBC was the strongest predictor, explaining 34% of behavioural intention. However, behavioural intention and PBC did not explain unit compliance. This was unexpected, as it had been anticipated and demonstrated that individual staff perceived greater control over the offer of contraception compared with the assessment appointment. Yet the interviews with lead gynaecologists had suggested that the availability of contraception and skills of clinical staff substantially influenced compliance with the recommendation. The practical implication is that enhancing the PBC of individual staff by providing training should be accompanied by organisational changes (such as increasing the range of contraception available) to increase the proportion of women discharged with contraception supplied.

The focus of interventions. The need to specify the main components of the strategy in advance limited the scope to alter planned interventions or select new interventions. This was partly related to the need to specify provisional interventions as part of the project funding application to the CSO. However, interventions such as the educational meetings had to be planned at least several weeks in advance to fit in with local postgraduate programmes. The project also addressed what range of interventions a national clinical effectiveness programme could feasibly deliver. It was important to retain and test this intervention as much of SPCERH's work programme is based upon audit and feedback.

The final interventions selected largely focused on individuals and teams of clinical staff involved in the provision of abortion care. According to the TPB survey, most staff involved in providing abortion care already had strong intentions to follow the guideline recommendations. This 'ceiling effect' reduced the potential for interventions targeted at health professionals to improve guideline adherence by increasing behavioural intentions.

Relatively high levels of pre-intervention compliance were measured for range of recommendations (e.g. antibiotic prophylaxis or screening for lower genital tract organisms) previously associated with low compliance in an earlier national audit (203). It is possible that,

once accepted by gynaecologists, such recommendations were less difficult to implement compared with chronic, complex organisational problems, e.g. reduction of waiting times for assessment appointments.

Certain aspects of the strategy were relevant to organisational barriers. For example, during delivery of the intervention lead gynaecologists were reminded that they could share audit data with other clinical colleagues and managers to highlight the need for change. Suggestions on how to address factors external to the units were also shared, e.g. the introduction of routine reminders to practices contributing to delays in referrals by failing to use telephone referral systems.

Had more time and flexibility been available, it is uncertain what interventions could have been designed and delivered to tackle such recommendations associated with lower compliance. Given that barriers ranged from individual through to team and organisational levels, a multi-level approach might have been more appropriate. However, little rigorous evidence is available on the effectiveness of interventions, such as Continuous Quality Improvement (CQI), targeting the organisational end of this spectrum (236;237). More importantly, the necessary time, resources and expertise were not available to test such approaches within the context of this trial.

Strengthening interventions. There could have been a greater emphasis on strengthening promising aspects of interventions to tackle more remediable barriers. For example, compliance with the recommendation to record cervical smear history was generally low. This was mainly attributed to errors of omission, from poor recording or failing to take the history during assessment appointments. In this case the use of structured case records represents an appropriate intervention to prompt improved recording. The introduction or amendment of local structured records was (necessarily) left to the discretion of local gynaecologists. The extent to which changes were actually made to this process of care is reported in Chapter 7.

6.6.5 Unanswered questions and research needs

A behavioural theory was used in developing the content of the intervention and provided a greater understanding of the underlying barriers to change. Theories from behavioural sciences are increasingly being used to investigate professional and organisational practice. Theoretical approaches to implementation research may focus on factors within individual health care professionals that are associated with adherence to evidence-based health care, or organisational factors. Process Modelling in ImplEmentation research (PRIME), an MRC-funded collaborative programme of work, aims to develop an understanding of individual professional behaviour in order to identify what processes should be targeted in interventions to change behaviour (A

Walker, personal communication). Experience from developing the ImpACT strategy underlines the need to extend similar work towards team and organisational levels. The long term aim is to develop diagnostic tools that can provide an empirical basis for the most appropriate selection of interventions and level to target (e.g. individual, team or organisational) given specific barriers and circumstances.

6.7 Conclusion

Experience from the development of the ImpACT strategy highlights lessons relevant to the development of other implementation strategies. More than one approach may be required to identify potential barriers and needs, especially if both individual and organisational factors are important. Yet, this can be relatively resource-intensive. A range of barriers to the implementation of the induced abortion guideline was identified. The key issues were to what degree these different barriers were remediable to interventions and at what level such interventions should take place. Approaches solely aiming to influence individual staff to follow the guideline recommendations were likely to be ineffective or counter-productive because of a 'ceiling' effect around behavioural intention. In selected units, there may have been scope for increasing staff behavioural intentions by presenting the offer of an assessment appointment within five days of referral as the professional norm and increasing staff control over the provision of contraception at discharge. However, such actions were unlikely to be effective if wider organisational barriers were not addressed.

Sufficient time needs to be integrated within project plans to allow reflection upon findings and planning of the definitive intervention components. The final strategy consisted of audit and feedback, educational meetings, dissemination of a model structured case record and promotion of patient information. The format of the interventions was negotiated with local lead gynaecologists and the educational content refined in the light of identified barriers and predictors of intention. Ideally, the range of available interventions should be sufficient to allow the selection of those most relevant to identified remediable barriers. However, even where choice is restricted, there may be scope to strengthen more promising aspects of available interventions.

Chapter 7

A randomised evaluation of a strategy, delivered within a national clinical effectiveness programme, to improve implementation of a clinical guideline on women requesting induced abortion

7.1 Summary

Chapter 6 described the development of a strategy to promote implementation of the Royal College of Obstetricians and Gynaecologists guideline, *The Care of Women Requesting Induced Abortion*. This chapter reports an evaluation of the effectiveness and efficiency of the strategy, the Improving Abortion Care Trial (ImpACT).

The study design was a two-arm cluster randomised controlled trial. Pairs of gynaecology units matched by pre-intervention performance were randomly allocated to the intervention or control arms. All fellows and members of the RCOG in the control units received printed summaries of the guidelines alone. The intervention units received a tailored package, deliverable by a national clinical effectiveness programme, comprising audit and feedback, educational meetings, dissemination of structured case records, and promotion of a patient information booklet.

Twenty-six gynaecology units in Scotland participated. The primary outcomes were compliance with five guideline recommendations representing key aspects of quality of care. Outcome data were collected from a review of case notes and a patient survey. Process and cost data were also collected from interviews and documented notes.

1474 case notes from 25 gynaecology units were reviewed. No post-intervention differences between intervention and control units were observed with respect to any of the primary or secondary outcomes. There was no evidence that the ImpACT strategy reduced variations in compliance among intervention units compared with controls.

1028 / 2109 patient questionnaires were returned completed, a response rate of 49%. Significantly fewer women in the intervention group recalled having been counselled about the complications and possible sequelae of abortion (OR 0.45, 95% CI 0.25 to 0.80). No other significant differences between the intervention and control groups were observed with respect to compliance with recommendations or satisfaction with care received.

The average cost of the intervention per gynaecology unit was £2067, with the audit and feedback component accounting for half this cost. No significant differences in primary outcomes meant that a cost-effectiveness analysis was not justified. There was no evidence that intervention units planned or made more changes to service provision than control units.

This tailored multi-faceted package to promote implementation of a clinical guideline had no effect on the quality of induced abortion care. The most plausible explanations for the lack of effect include the timing of the study in relation to publication of the guideline (with limited scope for improvement in relation to several recommendations), and the intensity and appropriateness of the intervention.

7.2 Introduction

7.2.1 The design and evaluation of implementation strategies

A range of interventions exists to promote improved clinical practice and reduce inappropriate variations. The interpretation of the substantial body of literature on implementation strategies is hindered by the poor methodological quality and limited generalisability of primary studies. Chapter 1 highlighted lessons from systematic reviews for the design of implementation strategies and their evaluation. Several features of the Improving Abortion Care Trial (ImpACT) were designed to address such shortcomings.

Validity of change. In previous primary studies, the clinical benefits or relevance of improvements in practice have sometimes been of uncertain or doubtful value. Proposed changes in clinical and organisational practice should ideally be based upon robust evidence. Guideline recommendations are more likely to be valid if produced by national or regional guideline development groups according to rigorous and explicit methods (238). The RCOG guideline, *The Care of Women Requesting Induced Abortion*, was developed by a multidisciplinary group according to rigorous criteria, including explicit methods of appraising and grading evidence (239). The guideline recommendations were graded as follows:

> **A** Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation.
>
> **B** Requires the availability of well conducted clinical studies, but no randomised clinical trials on the topic of the recommendation.
>
> **C** Requires evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates an absence of directly applicable clinical studies of good quality.
>
> **Good practice points.** Recommended best practice based on the clinical experience of the Guideline Development Group.

Combining interventions. Earlier reviews suggested that combining interventions increased the likelihood of successful implementation, perhaps because of their ability to overcome more than one barrier to change (20). However, there is little evidence that increasing combinations of interventions augments effect sizes (103). It is also questionable whether any additional potential benefits associated with combinations of interventions outweigh their greater costs.

Tailoring of implementation strategy. It has been suggested that implementation strategies should be based upon identified needs and barriers, allowing more rational selection or tailoring of interventions (19;101;208;240;241). Although intuitively attractive, there is little empirical evidence on the effectiveness of this approach. The design of the ImpACT strategy was based upon the application of a behavioural theory to understand barriers to change (Chapter 6).

Generalisability. Much previous research is of limited generalisability: out of 239 guideline implementation studies identified in the review of guideline implementation strategies, only 8 (3%) took place in UK secondary care (103). Eight studies were identified that evaluated combinations of educational materials, educational meetings and audit and feedback against no control interventions. The observed effects were small – with a median absolute improvement in outcomes across three cluster randomised controlled trials of 3%. Only two of these eight studies, both time series analyses, took place UK secondary care settings. One US cluster RCT, set in primary care, evaluated a combination of educational materials, educational outreach, educational meetings, and audit and feedback against no control and found an absolute improvement in outcomes of 6% (242). ImpACT represented the first cluster randomised evaluation of a similar combination of interventions in UK secondary care.

Rigorous study design. Cluster randomised trials generally represent the most rigorous design available to test interventions to change professional and organisational behaviour. Previous studies have been associated with a number of weaknesses, particularly failures to account for clustering effects in design and analysis (243). Other improvements in design, such as the collection of baseline data on performance and the use of minimally intrusive methods of data collection, can also strengthen the design of randomised evaluations (244). The design of ImpACT met these criteria.

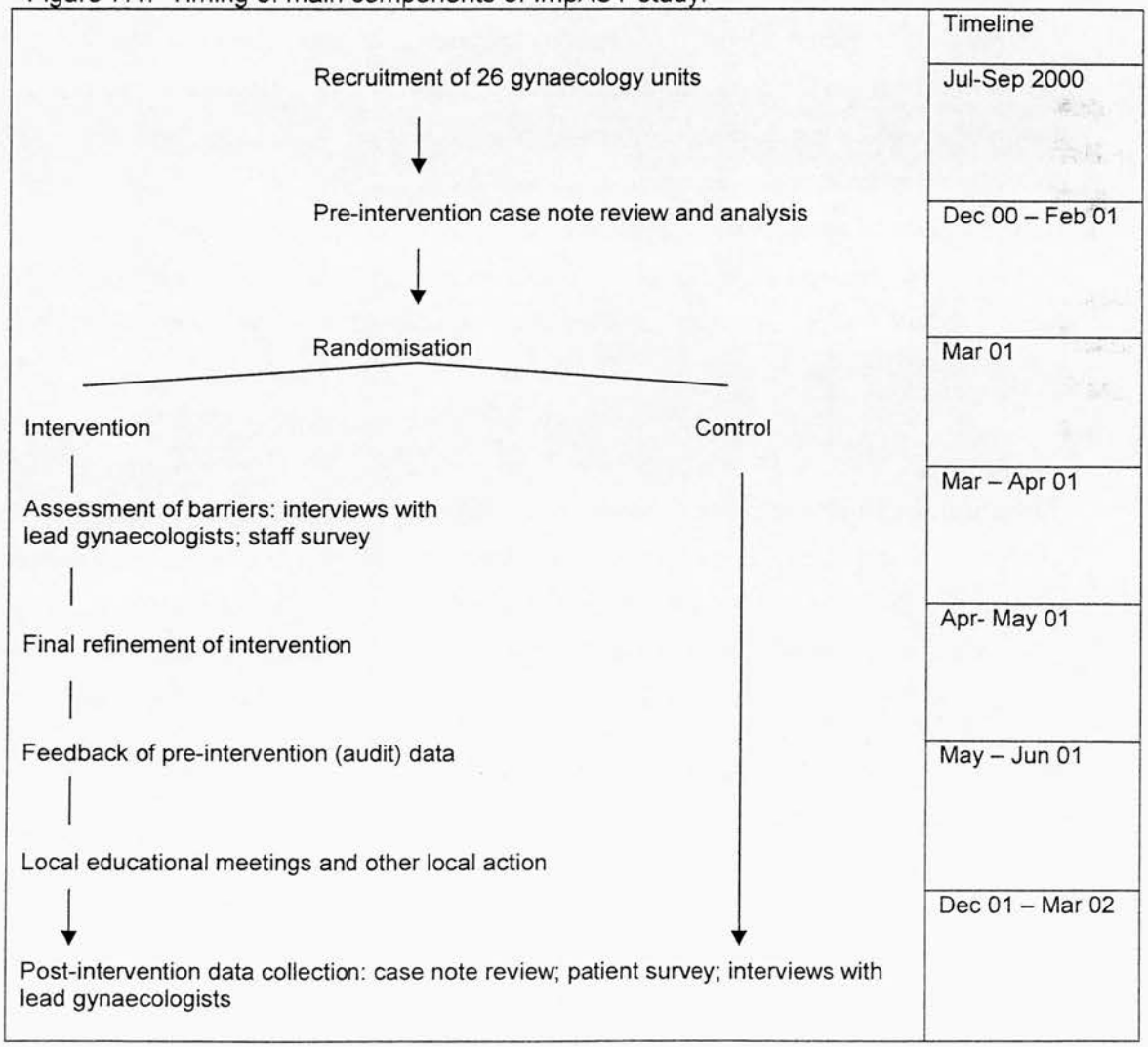
Economic evaluation. Only 29% of comparisons assessed in the aforementioned review reported any economic data (103). Overall the methods of the economic evaluations and cost analyses were poor. As well as the direct costs of changing clinical behaviour, little work has been done on the wider effects on health services following implementation – which may be affected by the choice of the guideline topic or recommendations (245). The design of ImpACT incorporated an economic evaluation.

7.2.2 Aim and research questions

ImpACT aimed to evaluate the effectiveness and efficiency of a multi-faceted intervention delivered by SPCERH to improve implementation of the RCOG guideline, *The Care of Women Requesting Induced Abortion*. The study set out to address the following questions:

- How effective is a package of clinical guidelines and a tailored intervention delivered within the context of a national clinical effectiveness programme, compared with the guidelines alone, in improving the care of women requesting induced abortion?
- What are the costs of supporting the dissemination and implementation of a guideline with such a package of measures?
- What are the cost implications of different levels of adherence to the guideline and do these offset the costs of the intervention package?

Figure 7.1. Timing of main components of ImpACT study.



7.3 Methods

7.3.1 Study design

The study design was a two-arm cluster randomised controlled trial. The main components of the study are summarised in Figure 7.1. The design and planning of the trial were supervised by a multidisciplinary steering group (Appendix 7A).

7.3.2 Study setting and population

The study population comprised all gynaecology units in Scotland responsible for providing induced abortion care.

7.3.3 Randomisation

Randomisation occurred at the level of gynaecology units. Units were initially stratified by throughput and then matched by baseline performance with three of the guideline recommendations used to assess the main outcomes (see 7.3.6). This method of randomisation attempted to reduce pre-existing variations in practice between intervention and control units (246;247). The three recommendations were used in the following order to match randomised units: provision of an assessment appointment with five days of referral (matching correlation 0.99), antibiotic prophylaxis and/or genital tract screening (0.72), and cervical cytology history (0.56). The units in each matched pair were randomised to either intervention or control by an independent statistician.

During the planning of the study, NHS reforms in Scotland led to several mergers of the management of acute hospitals to form one acute NHS trust within each Health Board (248;249). This gave rise to a risk of contamination of the intervention if two or more gynaecology units within one NHS trust were allocated to intervention and control units. Contamination might have arisen, for example, from the establishment of joint protocols or educational meetings. Relevant clinical directors were telephoned to assess the potential for contamination. They indicated that the mergers would be in the early stages of developing joint management systems and that shared activities to improve clinical care were likely to be non-existent or minimal during the intervention and follow-up periods. Nevertheless, in implementing the intervention measures were taken to avoid contamination, e.g. avoidance of any joint educational meetings between gynaecology units in the same trust.

7.3.4 Intervention arm

All fellows and members of the RCOG received identical printed guideline summaries. The implementation strategy was described earlier (Chapter 6.5) and comprised audit and feedback, educational meetings, review of structured case records and promotion of a patient information booklet. The format and content of the interventions were refined according to identified barriers and local needs.

7.3.5 Control arm

In gynaecology units randomised to the control arm, all fellows and members of the RCOG received identical printed guideline summaries. Following the collection of pre-intervention data and randomisation, no further contact was made with these units until post-intervention data collection started.

7.3.6 Primary outcomes

The primary outcomes were determined in advance of pre-intervention data collection. As far as possible, each outcome was selected to fulfil the following criteria: clinical importance; easily definable; potential for improvement; sufficiently common to provide reliable data; and responsive to the planned intervention (250;251). Five guideline recommendations encompassing different aspects of care were subsequently selected. Data measuring compliance with each of these recommendations were available from case notes.

Ideally, all women are offered an assessment appointment within five days of referral. This Grade C recommendation related to the organisation of services. The earlier in pregnancy an abortion is performed, the lower the risk of complications. The absolute risk of complications at the time of abortion is low (0.7%)(233). The risk of serious complications increases 1.4 times for every 2 week increment in gestation beyond 12 weeks (234). The Birth Control Trust suggested five days as an appropriate target between referral and assessment, a target endorsed by a consensus survey of Scottish gynaecologists (232). The last known measure of pre-study compliance (as opposed to pre-intervention compliance described in Chapter 6) was 49% across ten Scottish gynaecology units in 1992 (149).

Assessment prior to induced abortion may be viewed as an opportunity to ascertain each woman's cervical cytology history. This Good Practice Point related to pre-abortion management. Ideally, abortion care should provide holistic sexual health care. Checking cervical smear status offers an opportunity to discuss the value of screening and explore any concerns with women whose smears are overdue. Women requiring a smear can be reminded to

attend their own general practices following the abortion. A sub-group of women attending for abortion care may make poor use of preventative services and subsequently represent a high risk group for cervical cancer. Pre-study compliance with this recommendation was 61% (149).

Abortion care should encompass a strategy for minimising the risk of post abortion infective morbidity. Appropriate strategies include antibiotic prophylaxis (Grade A) or screening for lower genital tract organisms with treatment of positive cases (Grade B). This recommendation also related to pre-abortion management. Genital tract infection is a recognised complication of abortion, occurring in up to 10% of women not receiving antibiotic prophylaxis. Long term sequelae of post-abortion infection include tubal infertility and ectopic pregnancy. Universal antibiotic prophylaxis halves the risk of infective morbidity (252) and, by itself, is the most cost-effective strategy for minimising short term infective sequelae of abortion (253). Universal prophylaxis with screening allows an opportunity for contact tracing (254). Pre-study compliance with this recommendation was 31% (149).

Misoprostol given vaginally is a cost-effective alternative to gemeprost (in early and mid-trimester medical abortions and cervical priming). This Grade A recommendation related to abortion procedures. Misoprostol is as effective as gemeprost (255-261). Gemeprost costs approximately £20 per dose compared with around £1 for misoprostol. No data were available on pre-study compliance.

Contraceptive supplies should have been offered if required. The chosen method of contraception should be initiated immediately following abortion. This Grade B recommendation related to after care. Ovulation occurs within a month of first trimester abortion in over 90% of women (262). In 1999, 24% of 12,167 women undergoing induced abortion in Scotland had experienced at least previous one abortion (ISD data). The provision of contraception is an essential component of preventive care following abortion. Pre-study compliance with this recommendation was 54% (149).

7.3.7 Secondary outcomes

The secondary outcomes mainly comprised compliance with 30 of the remaining guideline recommendations (Table 7.1). In approving funding for the original proposal, the CSO Health Services Research Committee requested an assessment of women's views as part of the outcomes. For several recommendations (e.g. relating to provision of information), a patient survey represented the most appropriate, if not the only, way to ascertain compliance.

The patient survey also assessed six other secondary outcomes not directly related to the guideline recommendations. Four of these outcomes were taken from a North American survey of women following abortion: staff competency; the counselling process; staff sensitivity; and a global rating of satisfaction (263). The other two outcomes were derived from a previous survey of Scottish women: the sufficiency of time and help from staff to make decisions; and whether women now felt that the decision made was right for them (264).

7.3.8 Data collection

Primary and secondary outcome data were available from the case note review, the patient survey, or both (Table 7.1). Altogether, 20 recommendations were assessed by the case note review only, 5 by the patient survey only, and 10 by both.

Table 7.1. Sources of data to measure compliance with guideline recommendations.

Recommendation	Case note review	Patient survey
Organisation of services		
Ideally, all women are offered an assessment appointment within five days of referral (primary outcome)	X	X
As a minimum standard, all women are offered an assessment appointment within two weeks of referral	X	X
Ideally, all women can undergo the abortion within seven days of the decision to proceed being agreed	X	X
As a minimum standard, all women can undergo the abortion within two weeks of the decision to proceed being agreed	X	X
As a minimum standard, no individual woman need wait longer than three weeks from her initial referral to the time of her abortion	X	X
In the absence of specific medical, social or geographical contra-indications, induced abortion may be managed on a day-case basis	X	
Information for women		
Verbal advice must be supported by accurate, impartial printed information which the woman considering abortion can understand and may take away and read before the procedure		X
Information for women and professionals should emphasise the duty of confidentiality by which, as for any form of health care, all concerned with the provision of induced abortion are bound		X
Professionals providing abortion services should possess accurate knowledge about possible complications and sequelae of abortion. This will permit them to provide women with the information they need in order to give genuinely informed consent		X
Pre abortion management		
Pre-abortion assessment should include appropriate blood tests	X	
It is not cost-effective routinely to cross-match women undergoing termination of pregnancy	X	
Assessment prior to induced abortion may be viewed as an opportunity to ascertain each woman's cervical cytology history (primary outcome)	X	
Women who have not had a smear within the interval recommended in their local programme may be offered a smear taken opportunistically	X	
Ultrasound scanning is not considered to be an essential prerequisite of abortion in all cases	X	
Abortion care should encompass a strategy for minimising the risk of post abortion infective morbidity (primary outcome)	X	

Table 7.1 (continued). Sources of data to measure compliance with guideline recommendations.

Recommendation	Case note review	Patient survey
Abortion procedures		
Ideally, abortion services must be able to offer a choice of recommended procedures for relevant gestation bands		X
Medical abortion is an appropriate method at gestations of <7 weeks / Conventional suction termination should be avoided at <7 weeks	X	
For early medical abortion, a dose of 200mg of mifepristone, in combination with a prostaglandin is adequate	X	
Use of conventional suction termination at gestations of 7-15 weeks if appropriate or preferred	X	
For women presenting between 7-15 weeks' gestation, suction termination may be safer under local anaesthesia than under general anaesthesia	X	
Misoprostol is a cost-effective alternative for gemeprost (early and mid-trimester medical abortion, and cervical priming; primary outcome)	X	
Cervical preparation is beneficial prior to suction termination and should be routine if the woman is aged under 18 years or at a gestation of >10 weeks	X	
For mid-trimester medical abortion, a dose of 200mg of mifepristone is adequate	X	
Surgical evacuation of the uterus is not required routinely following mid-trimester medical abortion	X	
Mid-trimester abortion by dilatation & evacuation (D&E), preceded by cervical preparation, is safe and effective when undertaken by specialist practitioners	X	
For women presenting at greater than 15 weeks' gestation, as an alternative to D & E, services may prefer to offer medical abortion	X	
Managing complications of abortion		
Oxytocics are effective in reducing intra-operative blood loss	X	
In cases of suspected uterine perforation laparoscopy is the investigation of choice	X	
After care		
Anti-D IgG should be given to all non-sensitised RhD negative women following abortion	X	
After an abortion, women must be given a written account of the symptoms they may experience and a list of those that would make an urgent medical consultation necessary. They should be given a 24 hour help-line telephone number to use if they feel worried about pain, bleeding or high temperature		X
A follow-up appointment (either within the abortion service or with the referring clinician) within two weeks of the procedure should be offered to each patient following abortion	X	X
Before she is discharged following abortion, future contraception should have been discussed with each patient	X	X
Contraceptive supplies should have been offered if required. The chosen method of contraception should be initiated immediately following abortion (primary outcome)	X	X
Sterilisation can safely be performed at the time of induced abortion. However combined procedures are associated with higher rates of failure and of regret	X	X
It is safe and effective to insert an IUCD for contraceptive use immediately following induced abortion	X	X

7.3.8.1 Case note review

Case identification. Data collection from women's case notes took place over two phases: a pre-intervention sample of up to 50 abortion cases per gynaecology unit; and a post-intervention sample of up to 75 per unit. Cases were identified for two periods: 1st September to 30th November 2000 pre-intervention; and 1st September to 30th November 2001 post-intervention.

Cases were identified retrospectively from ward admission diaries. Women admitted for spontaneous miscarriage or for induced abortion because of fetal anomalies were excluded. All consecutive cases were included from smaller units, where no more than 50 and 75 cases were available over the two phases. Random quota sampling was necessary for units with greater throughputs.

Data collector training. Locally employed hospital nursing or clerical staff extracted clinical information from case notes. The majority of these staff attended one of two training days. Training included small group work during which participants jointly abstracted data from case notes from their own gynaecology units. The remaining data collectors received a standard training package during visits (by the author) to gynaecology units. The data collection form was developed and modified following pre-testing with the data collectors (Appendix 7B). All data collectors received a booklet detailing key aspects of case note retrieval, data abstraction and a research office telephone number to contact with queries.

The feedback of pre-intervention results to intervention units provided an opportunity to verify data from the case note reviews. The main error detected was the failure of data collectors in three units to identify all women who had received antibiotic prophylaxis. This primarily occurred because treatments were sometimes written up on day case sheets rather than prescription sheets. Subsequently, prescribing policies in control units with low levels of compliance were checked and the database amended as required. More explicit instructions on the abstraction of such data from case notes were included in the post-intervention data collection form.

Protection of confidentiality. Recognising the sensitivity of this clinical issue, the data collection form contained no items (e.g. name, address, hospital number or date of birth) that could have enabled the identification of individual cases. Within each hospital, local data collectors assigned a unique study number to each case, based upon numbers listed on the case identification forms (Appendix 7C). The data collectors held a master list of patient case note numbers and the data abstraction form numbers. This helped to avoid retrieval of duplicate case notes and facilitated later checks of any anomalous or erroneous data. Thus data returned to the project team were anonymised. Data received for analysis were held within a secure database in the SPCERH office.

As in other trials requiring organisational level recruitment, written consent for access to patient case notes was obtained from appropriate 'guardians', namely the clinical directors and

consultant gynaecologists responsible for the care of women undergoing abortions (265). Only one consultant refused permission for access to patient case notes.

7.3.8.2 Patient survey

Questionnaire development. The questionnaire was primarily developed to assess gynaecology units' compliance with guideline recommendations from the patient perspective (Appendix 7D). The patient survey assessed patient recall of information provided. For one recommendation, concerning the provision of accurate information about possible complications and sequelae of abortion, a summary variable was derived from the following items:

- Whether doctors or nurses talked to women about possible problems or complications after the abortion
- Which of the following possible complications had been mentioned: excessive bleeding following the abortion (haemorrhage); damage to the uterus, or womb, requiring a more major operation (uterine perforation); failure of the abortion method (and need for another abortion procedure); and pelvic infection.

For women who had undergone surgical abortions, compliance with the recommendation was met if all five questions were answered 'yes'. For medical abortions, compliance was met if four questions (having excluded uterine perforation which is only relevant to surgical abortions) were answered 'yes'.

Questions assessing other aspects of care were drawn from previous surveys (263;264). The following summary variables and items, each rated on a five-point Likert scale assessing agreement with statements, from Zapka et al were incorporated:

- Staff competency, comprising four items assessing agreement on a five-point scale with the following statements: the clinical care I received was excellent; my confidentiality was protected; the staff treated me with respect; the staff were professional and thorough.
- The counselling process: there was too much emotional talk; there was too much medical talk; the staff asked too many questions.
- Staff sensitivity: the staff treated me as a whole person; the staff weren't afraid to discuss emotional issues.

These items have been demonstrated to have good internal consistency, with Cronbach's alpha coefficients ranging from 0.73 to 0.99 (263). As in the study by Zapka et al, global satisfaction

was rated on a five-point scale according to whether respondents agreed with the statement, "There are some things about the medical care I received that could be better."

Following this initial development, the content of the questionnaire was pre-tested on medical, nursing and midwifery staff involved in abortion care and a representative from the Family Planning Association. Minor modifications were subsequently made. The resulting draft was then pre-tested during one-to-one interviews with a convenience sample of women undergoing medical and surgical abortions. Women were invited to state whether any aspect of the questionnaire required clarification or seemed insensitive or inappropriate. Changes were required to clarify some of the questions.

To protect anonymity, the survey form only allowed identification of the gynaecology unit attended. To allow comparison of baseline characteristics, women were asked to provide information about their age, gestation of pregnancy at the time of the abortion procedure and postcode sector (the postcode minus the last two letters). The latter data were to be used to derive Carstairs Deprivation indices.

Sampling frame. All women attending Scottish gynaecology units for an induced abortion were eligible except for those unable to read and understand English. The survey commenced six months following the intervention activities and took place over four months. The first month effectively represented a 'run-in' phase because of postal delays affecting the receipt of questionnaire packs by several units.

Survey administration and consent. Conducting a survey of this client group presented a range of methodological and ethical problems. Some women undergoing induced abortion may experience anxiety and distress. The conduct of the survey was designed to minimise any additional burden imposed by participation in research.

The first issue concerned timing. Women may have been able to provide more considered (and possibly valid) views about their care later after discharge. However, there was a risk that surveying women a month following discharge from abortion care would have led to a reduced response rate. It was also considered inappropriate to contact women by post because of the risk of breaching confidentiality. The survey was therefore administered at the point of discharge following the abortion procedure.

The second issue concerned consent. There was a risk that selection bias might have occurred had clinical staff been responsible for consenting women. For instance, clinicians in the

intervention group could have recruited a different group of women from those clinicians in the control group (e.g. those more satisfied with care received). Use of a consent form was also considered inappropriate because it might facilitate later identification of individual women. Therefore, by choosing whether or not to complete the questionnaires, women were able to give implied consent.

The patient survey form only allowed identification of the gynaecology unit attended. All women received a sealed envelope, containing a questionnaire stapled to an SAE, as part of the administrative procedure during discharge. Women who opted to participate in the survey retained the option of handing (sealed) it to staff or posting it themselves. In this way, women's responses could be kept confidential from clinical staff. Clinical staff were informed about the study in case women required further information.

The conduct of the survey was piloted in two gynaecology units (one intervention and one control) to test the feasibility and acceptability of administration to both staff and the women. Out of 120 questionnaires administered, 48 (40%) were returned, an acceptable response rate in comparison with similar surveys (149;263). No administration problems were reported.

7.3.8.3 Economic evaluation

Costs. Data on costs of the strategy were elicited and categorised in relation to its development, dissemination and implementation (196). Development costs included those costs that would not necessarily need to be replicated in future use of the strategy in gynaecology units. These costs consisted of centrally incurred costs in designing aspects of the intervention such as the audit and feedback process. The costs were apportioned equally to each unit. Such costs conceivably could be incurred in the replication of the intervention strategy by a national clinical effectiveness programme, or equivalent.

The intervention costs were estimated separately for each of the five components of the implementation strategy:

- Audit and feedback
- Identification of barriers
- Educational meetings
- Dissemination of a model structured case record
- Promotion of a patient information booklet

For the intervention arm, data were collected during each significant contact, namely the meetings with lead gynaecologists and local educational meetings. Structured notes were taken to record the length of each contact and the number and grade of local staff involved (Appendix 7E). Action plans agreed with each unit following the educational meetings were recorded. Some of the centrally incurred costs (e.g. time taken to plan the audit) were estimated retrospectively following discussions among project team staff. The amounts of staff time, including travelling time, at each grade for the personnel involved in each stage of the intervention were estimated and combined with figures for per hour salary rates. The rates used were the mid-point on the salary scale for each grade with the addition of on-costs for superannuation and national insurance. Other costs included catering at the various meetings and any travel expenses incurred by intervention staff to visit the units, and administration costs such as printing, postage and photocopying of data collection forms audit reports.

Primary outcomes. These comprised differences in the level of compliance with each of the five key recommendations (section 7.3.6).

Secondary outcomes. These comprised differences in the level of compliance with each of the other recommendations as measured by the case note review and patient survey (section 7.3.7).

Post-intervention, a semi-structured telephone survey took place with lead gynaecologists in both control and intervention units. This survey ascertained what efforts had been made to change local services in the six months since the start of the intervention phase. The interview schedule covered action taken specifically in relation to the five key recommendations (Appendix 7F). The collection of this data also enabled an exploration of differences in compliance with recommendations among control and intervention units that might be related to reported local activity following the implementation strategy.

7.3.9 Sample size

Case note review. The original sample size calculations were based upon the anticipated recruitment of twenty gynaecology units. The sample size for the case note review was based upon a cluster level analysis that matched gynaecology units by pre-intervention performance and randomised each of the matched pairs of units to intervention or control (266). Using data from the Gynaecology Audit Project in Scotland (GAPS), the average compliance across 10 hospitals with a key RCOG guideline recommendation (assessment appointment within 5 days of referral) was 49%. Based upon this outcome, it was expected that the hospitals could be matched so that the correlation between the matched pairs exceeded 0.7. Using these characteristics, a study with 20 hospitals and 75 cases per hospital at follow up would have had 80% power at 5%

significance level to detect a difference of 20% in average compliance between intervention and control hospitals. Two developments led to the modification of this approach. Firstly, 26 units were recruited. Secondly, for the five primary outcomes, none of the correlations within the matched pairs were sufficiently strong (over 0.7) to warrant a matched analysis (Table 7.2). Such an analysis would have had 55% power to detect a 20% difference. Therefore, the matching was broken and the study analysed as two independent groups (267), resulting in 82% power to detect a difference of 20% in the definitive analysis.

Table 7.2. Pre- to post-intervention correlations within matched pairs for key outcomes.

Recommendation	**Pearson correlation**	**Significance (2 tailed)**
Appointment with a gynaecologist within five days of referral	0.53	0.08
Ascertainment of cervical cytology history	0.40	0.20
Antibiotic prophylaxis or screening for lower genital tract organisms	0.20	0.54
Misoprostol cost-effective alternative to gemeprost	- 0.10	0.76
Offer of contraceptive supplies if required prior to discharge	0.39	0.21

Patient survey. The sample size for the patient survey was based upon a patient level analysis correcting for clustering using multilevel modelling. This required 1000 patients (i.e. 50 patients from each of 20 hospitals) to detect a difference between units of 20% (44% versus 64%), with 80% power and a 5% significance level. This assumed an intra-cluster correlation (ICC) of less than 0.1. There were no previous ICC estimates relating to patients' experiences of and satisfaction with secondary care. However a primary care study of patients' satisfaction with out-of–hours primary care observed ICCs of the order of 0.05 (268) which were similar to the order of ICCs observed in outcome surveys (269).

7.3.10 Data entry

All data were entered onto an Access Database. For the case note review, the reliability of data entry was checked by re-entering 10 selected items for a 5% random sample of records. No miscoded entries were found out of 72 records and 720 entries. For the patient survey, data were also re-entered for a 5% random sample of records. Based upon 48 records and 32 items per questionnaire, one entry was miscoded out of 1536, an agreement of 99.9%.

7.3.11 Analysis

Case note review. The primary analysis of the data was planned to estimate the effect of the multi-faceted strategy on clinical practice. The case note data were analysed as described in Appendix 7G.

Generalised estimating equations (GEE) represented the principal analysis technique adopted. This is a technique for use with hierarchical data sets (patients within gynaecology units in this case) and allowed variation to be modelled separately at each level (270). Given the difficulties in interpreting and adjusting for baseline in cluster trials with cross sectional binary measurements (271), the *a priori* analysis strategy (272) was to compare the difference between the compliant proportions in the post intervention data only. It was noted that, in this case, adjusting for baseline using the log odds of the pre-intervention compliance scores as a covariate made no difference to the size of effects.

Where compliance rates were high (>90%) or low (<10%), differences between the groups were tested for on the log-odds scale using the Mann-Whitney test. The exponential of the difference between the medians was then taken to give an odds ratio, as recommended by Ukoumunne and Thompson (271). All results are presented as odds ratios.

It was possible that the ImpACT strategy might have reduced variations among intervention units compared with control units, i.e. clinical care became more uniform. Levene's test was therefore used to compare equality of variances between the intervention and control units (273).

Analysis was by 'intention to treat', in that all women managed by gynaecology units allocated to the intervention were analysed as study patients, irrespective of whether or not the gynaecology unit utilised the intervention fully. Information on the uptake of the intervention was used to explore the impact on any changes in clinical practice.

Patient survey. The analysis was similar to that for the case note study in that it allowed for clustering effects and was based upon intention to treat. The patient survey outcomes were analysed as described in Appendix 7H. The survey also collected data about age and gestation at the time of abortion, permitting two comparisons to assess bias and generalisability. Firstly, comparison between the intervention and control groups allowed the detection of systematic differences that might be related to selective recruitment. Secondly, the characteristics of the patient survey respondents were compared with those of women in the case note review.

The number of patient survey packs sent to each gynaecology unit was recorded. The denominator used to calculate the survey response rate was derived by subtracting the number of packs remaining at the end of the survey period from the number sent out to each unit.

Economic evaluation. The evaluation was planned to address the costs and benefits of guideline dissemination. This was appropriate on the assumption that implementation of the guideline is beneficial (since the recommendations were derived using a rigorous methodology) and that findings on the costs and benefits of the intervention should be generalisable to the implementation of other clinical guidelines (274;275). In addition to the cost-effectiveness analysis, a balance sheet approach was planned to identify the costs and benefits of the intervention if the intervention was found to result in statistically significant improvements in the primary outcome measures (276).

7.3.12 Ethical approval

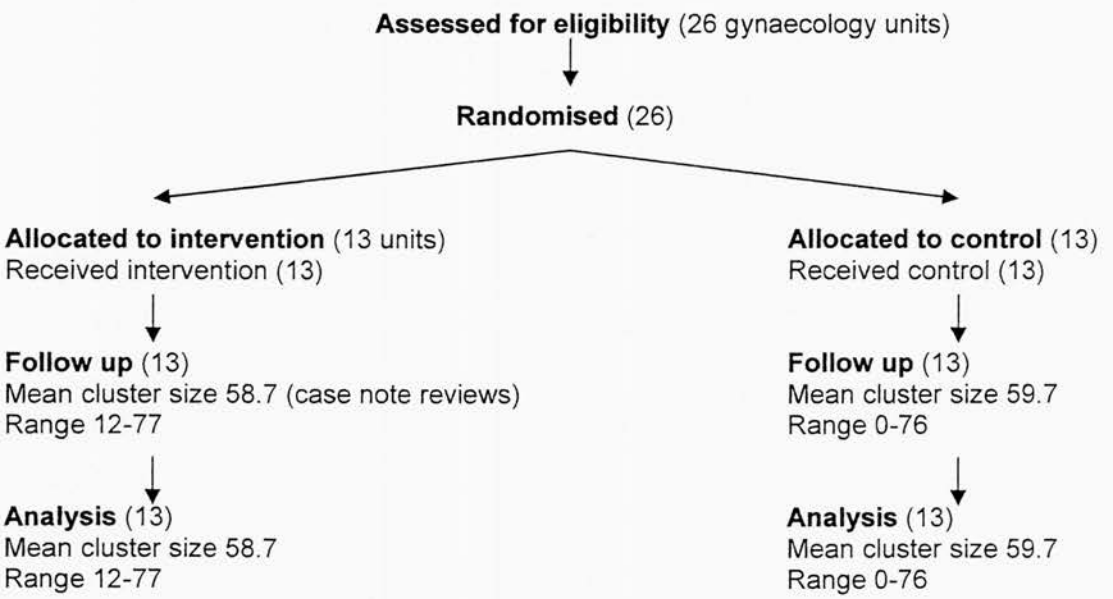
The study was approved by the Multi-centre Research Ethics Committee for Scotland and accepted by ten individual local research ethics committees (LRECs).

7.4 Results

7.4.1 Recruitment of gynaecology units

Figure 7.1 shows the recommended flow chart to facilitate reporting of cluster randomised trials (277).

Figure 7.1. Flow chart for cluster randomised trial.



Twenty-six gynaecology units were identified and recruited, comprising eight teaching and 18 non-teaching hospitals. Eighteen mainly served urban populations and eight semi-rural or rural populations. The number of abortions performed annually varied among units, with the majority of units (16) providing abortion care for between 101 and 500 women each year (Table 7.3).

Table 7.3. Annual number of induced abortions for 12 months over 1998-9 in Scottish hospitals (Source: Scottish Abortion Statistics, ISD).

Annual number of induced abortions	Number of hospitals
Less than 100	2
101 – 250	8
251 – 500	8
501 – 750	5
1001 – 1250	2
Over 2000	1
Total	26

7.4.2 Case note review

7.4.2.1 Number of cases identified

A total of 1474 eligible cases were assessed by the post-intervention case note review, 763 from the intervention arm and 711 from the control arm (Table 7.4). A mean of 56.7 cases was assessed per unit. No cases were identified in unit Z.

Table 7.4. Number of cases assessed for each gynaecology unit (presented in matched pairs as originally planned for the analysis).

Intervention units	Number of cases assessed per unit	Control units
A	12	0	Z
B	75	75	W
C	23	76	X
D	50	51	O
E	53	38	Q
F	75	75	S
G	58	59	U
H	75	56	R
I	67	75	N
J	75	48	V
K	75	52	T
L	48	31	P
M	77	75	Y
Total	763	711	Total

7.4.2.2 Patient and unit characteristics

Overall, intervention and control units were balanced with respect to patient and unit characteristics, except for a higher proportion of medical abortions in the intervention arm (Table 7.5). Pre-intervention unit compliance was compared between intervention and control units (Table 7.6). There were no statistically significant differences except for one outcome, antibiotic prophylaxis and screening, where the 95% confidence interval for the 1.5% difference between the medians was 0 to 8.3%.

Table 7.5. Post-intervention patient and unit characteristics.

Patient and unit characteristics	**Intervention** Weighted mean per cluster (SD)	**Control** Weighted mean per cluster (SD)
Patient age at time of referral (years)	24.9 (0.8)	25.5 (0.8)
Number of live and still births per patient	0.9 (1.1)	0.9 (1.2)
Number of miscarriages and previous induced abortions per patient	0.4 (0.8)	0.4 (0.7)
Estimated gestation at date of assessment appointment (weeks)	7.8 (0.6)	8.1 (0.7)
Method of abortion (proportion medical abortion)	49.8 (31.8)	44.3 (25.9)
Number of cases per cluster (SD)	58.7 (21.1)	59.7 (15.6)

Table 7.6. Pre-intervention unit compliance with five key outcome recommendations.

Recommendation (total number of eligible cases)	**Percentage intervention mean unit compliance (SD)**	**Percentage control mean unit compliance (SD)**	**Difference (95% CIs)**
Appointment with a gynaecologist within five days of referral (1041)	40.1 (19.5)	37.5 (17.3)	2.6 (-12.6 to 17.9)
Ascertainment of cervical cytology history (776)	50.5 (34.8)	55.6 (32)	-5.1 (-32.9 to 22.7)
Antibiotic prophylaxis or screening for lower genital tract organisms (1073)	100 (98 to 100)*	97 (90.3 to 100)*	1.5 (0 to 8.3)
Misoprostol cost-effective alternative to gemeprost (1069)	100 (93.1 to 100)*	98.6 (76.1 to 100)*	0 (-2 to 18)
Offer of contraceptive supplies if required prior to discharge (1073)	69.2 (22.0)	70.8 (24.7	-1.6 (20.9 to 17.7)

*The medians (inter-quartile range) and median differences for skewed data

7.4.2.3 Primary outcomes

There were no significant differences between intervention and control units for any of the five primary outcomes (Table 7.7). There was one non-significant trend favouring the intervention

group for one recommendation (antibiotic prophylaxis or screening for lower genital tract organisms, OR 1.70; 95% CIs 0.71 to 5.99). Mean unit compliance remained low for the offer of an assessment appointment within five days of referral. However, it was near optimal for two recommendations: antibiotic prophylaxis or screening for lower genital tract organisms; and the use of misoprostol as a cost-effective alternative to gemeprost.

The variances in post-intervention compliance were tested for equality using Levene's Test. There were significant results for two of the outcomes. For antibiotic prophylaxis or screening, there was significantly less variation within the intervention arm (SD 3.34) compared to the control arm (SD 11.31, p=0.02). This was principally related to low compliance in one control unit. For the use of misopostol, there was greater variation within the intervention arm (SD 14.39) compared to the control arm (SD 4.67, p=0.005). This was mainly related to lower compliance in three intervention units. Taken together, these findings suggest that the ImpACT strategy had no consistent effect on inter-unit variation for the primary outcomes.

Table 7.7. Primary outcomes based on case note review.

Recommendation (total number of eligible cases)	**Percentage intervention mean unit compliance (SD)**	**Percentage control mean unit compliance (SD)**	**Odds ratio (95% CIs)**
Appointment with a gynaecologist within five days of referral (n=1430)	35.5 (17.1)	40.5 (18.3)	0.89 (0.50, 1.58)
Ascertainment of cervical cytology history (n=1074)	58.5 (29.2)	60.2 (32.1)	0.93 (0.36, 2.40)
Antibiotic prophylaxis or screening for lower genital tract organisms (n=1474)	100 (95.2, 100)*	96.5 (90.1, 98.6)*	1.70 (0.71, 5.99)
Misoprostol cost-effective alternative to gemeprost (n=1472)	100 (86.5, 100)*	100 (97.3, 100)*	1.00 (0.27, 1.77)
Offer of contraceptive supplies if required prior to discharge (n=1474)	72.1 (17.7)	73.0 (24.9)	1.11 (0.48, 2.53)

*The medians (inter-quartile range) and median differences for skewed data

7.4.2.4 Secondary outcomes

No significant differences between intervention and control were observed with respect to any of the secondary outcomes measured from the case note review (Tables 7.8 to 7.12).

For pre-abortion management, there were two non-significant trends favouring the control group (Table 7.9). Firstly, the mean proportion of women appropriately undergoing opportunistic cervical smears was 12% lower in the intervention group (OR 0.79, 95% CI 0.26 to 2.44). Secondly, the mean proportion of women appropriately undergoing ultrasound scanning was 27.6% lower (OR 0.28, 95% CI 0.07 to 1.07).

For abortion procedures, there was one non-significant trend in favour of the intervention group (Table 7.10). The use of conventional suction termination at gestations of 7-15 weeks if appropriate or preferred was 4.8% higher (OR 1.34, 95% CI 0.55 to 3.25).

The numbers of eligible cases were too small to detect any differences between control and intervention units for the management of complications (Table 7.11).

The variances in post-intervention compliance were tested for equality using Levene's Test. There were two significant results for two of the 25 outcomes assessed. For the recommended dose of 200 mg mifepristone in early medical abortion, a dose of 200mg of mifepristone, there was significantly less variation within the intervention arm (SD = 0) compared to the control arm (SD 31.37, p = 0.03). This was principally related to low compliance in one control unit. Similarly, for the avoidance of routine surgical evacuation of the uterus following mid-trimester medical abortion, there was significantly less variation within the intervention arm (SD = 0) compared to the control arm (SD 11.11, p = 0.03), also related to low compliance in one control unit. For other recommendations, no consistent non-significant trends were found in favour of reduced variation among the intervention units. Overall, these findings provide little evidence that the ImpACT strategy influenced inter-unit variation for the secondary outcomes.

Table 7.8. Secondary outcomes on organisation of services based on case note review.

Recommendation (total number of eligible cases)	**Percentage intervention mean unit compliance (SD)**	**Percentage control mean unit compliance (SD)**	**Odds ratio (95% CIs)**
As a minimum standard, all women are offered an assessment appointment within two weeks of referral (n=1430)	89.7 (11.4)	88.5 (15.9)	1.15 (0.71, 1.89)
Ideally, all women can undergo the abortion within seven days of the decision to proceed being agreed (n=1459)	79.8 (7.8)	78.7 (13.5)	1.00 (0.59, 1.70)
As a minimum standard, all women can undergo the abortion within two weeks of the decision to proceed being agreed (n=1459)	96.0 (94.8, 98.1)*	96.0 (94.6, 98.1)*	0.96 (0.65, 1.92)
As a minimum standard, no individual woman need wait longer than three weeks from her initial referral to the time of her abortion (n=1432)	89.5 (83.1, 94.9)*	93.6 (83.6, 94.8)*	0.87 (0.37, 2.29)
In the absence of specific medical, social or geographical contra-indications, induced abortion may be managed on a day-case basis (1428)	93.1 (89.3, 96.1)*	95.3 (90.7, 96.3)*	0.86 (0.44, 1.60)

*The medians (inter-quartile range) and median differences for skewed data

Table 7.9. Secondary outcomes on pre-abortion management based on case note review.

Recommendation (total number of eligible cases)	**Percentage intervention mean unit compliance (SD)**	**Percentage control mean unit compliance (SD)**	**Odds ratio (95% CIs)**
Pre-abortion assessment should include appropriate blood tests (n=1474)	97.9 (86.5, 100)*	98.3 (96.2, 99.7)*	0.77 (0.22, 1.99)
It is not cost-effective routinely to cross-match women undergoing termination of pregnancy (n=1474)	100 (98.4, 100)*	100 (98.0, 100)*	1.31 (0.85, 2.59)
Women who have not had a smear within the interval recommended in their local programme may be offered a smear taken opportunistically (n=637)	63.4 (24.3)	75.5 (11.9)	0.79 (0.26, 2.44)
Ultrasound scanning is not considered to be an essential prerequisite of abortion in all cases (n=1474)	21.1 (32.4)	48.7 (40.7)	0.28 (0.07, 1.07)

*The medians (inter-quartile range) and median differences for skewed data

Table 7.10. Secondary outcomes on abortion procedures based on case note review.

Recommendation (total number of eligible cases)	**Percentage intervention mean unit compliance (SD)**	**Percentage control mean unit compliance (SD)**	**Odds ratio (95% CIs)**
Medical abortion is an appropriate method at gestations of <7 weeks / Conventional suction termination should be avoided at <7 weeks (n=233)	97.6 (68.8, 100)*	97.8 (69.6, 100)*	1.14 (0.20, 3.25)
For early medical abortion, a dose of 200mg of mifepristone, in combination with a prostaglandin is adequate (n=567)	100**	100 (96.2, 100)*	1.22 (0.77, 3.67)
Use of conventional suction termination at gestations of 7-15 weeks if appropriate or preferred (n=1212)	62.2 (23.0)	57.3 (33.3)	1.34 (0.55, 3.25)
For women presenting between 7-15 weeks' gestation, suction termination may be safer under local anaesthesia than under general anaesthesia (n=725)	0*	0***	n/a
Cervical preparation is beneficial prior to suction termination and should be routine if the woman is aged under 18 years or at a gestation of >10 weeks (n=207)	100 (87.0, 100)*	100 (96.2, 100)*	0.87 (0.33, 1.80)
For mid-trimester medical abortion, a dose of 200mg of mifepristone is adequate (n=92)	100**	100**	n/a
Surgical evacuation of the uterus is not required routinely following mid-trimester medical abortion (n=92)	100**	100****	n/a
Mid-trimester abortion by dilatation & evacuation (D&E), preceded by cervical preparation, is safe and effective when undertaken by specialist practitioners (no cases)	-	-	n/a
For women presenting at greater than 15 weeks' gestation, as an alternative to D & E, services may prefer to offer medical abortion (n=29)	100**	100**	n/a

*The medians (inter-quartile range) and median differences for skewed data
**All units 100% compliant
***All units 0% compliant except for one case in one unit
****All units 100% compliant except for one case in one unit

Table 7.11. Secondary outcomes on managing complications of abortion based on case note review.

Recommendation (total number of eligible cases)	Percentage intervention mean unit compliance (SD)	Percentage control mean unit compliance (SD)	Odds ratio (95% CIs)
Oxytocics are effective in reducing intra-operative blood loss (no cases)	-	-	n/a
In cases of suspected uterine perforation laparoscopy is the investigation of choice (n=3)	100*	0**	n/a

*Based upon two clusters of n=1; **Based upon one cluster of n=1.

Table 7.12. Secondary outcomes on after care based on case note review. (NB. All proportions expressed are medians because of skewed data.)

Recommendation (total number of eligible cases)	Percentage intervention median compliance (interquartile range)	Percentage control median compliance (interquartile range)	Odds ratio (95% CIs)
Anti-D IgG should be given to all non-sensitised RhD negative women following abortion (n=257)	100 (92.7, 100)	100 (90.3, 100)	0.87 (0.50, 1.39)
A follow-up appointment (either within the abortion service or with the referring clinician) within two weeks of the procedure should be offered to each patient following abortion (n=1474)	8.3 (2.7, 29.9)	6.6 (2.8, 26.3)	0.86 (0.19, 3.97)
Before she is discharged following abortion, future contraception should have been discussed with each patient (n=1474)	97.3 (94.7, 99.3)	98.4 (86.3, 100)	0.76 (0.28, 3.06)
Sterilisation can safely be performed at the time of induced abortion. However combined procedures are associated with higher rates of failure and of regret (n=1474)	100 (97.6, 100)	100 (100, 100)	0.97 (0.33, 1.34)
It is safe and effective to insert an IUCD for contraceptive use immediately following induced abortion (n=1474)	9.3 (5.3, 15.3)	8.1 (0.5, 15.8)	1.02 (0.57, 2.40)

7.4.3 Patient survey

7.4.3.1 Response rate

A total of 1028 questionnaires were returned completed out of 2109 distributed, a response rate of 48.7%. The response rate was lower in the intervention arm (45.1%; 482 / 1069) than in the control arm (52.5%; 546 / 1040). Response rates varied markedly among units, ranging from 3% to 98% (Table 7.13).

Table 7.13. Response rates to patient questionnaire by gynaecology unit (based upon original matched pairs).

Intervention units	Returned / Distributed questionnaires	% Response rate	% Response rate	Returned / Distributed questionnaires	Control units
A	4 / 8	50	-	0 / 0	Z
B	122 / 138	88	88	76 / 86	W
C	13 / 32	41	22	13 / 60	X
D	99 / 101	98	81	117 / 144	O
E	28 / 52	54	40	4 / 10	Q
F	32 / 64	50	61	118 / 194	S
G	27 / 50	54	30	15 / 50	U
H	33 / 64	52	11	5 / 47	R
I	37 / 59	63	77	174 / 227	N
J	23 / 109	21	10	5 / 52	V
K	55 / 182	30	12	6 / 50	T
L	3 / 38	8	10	2 / 20	P
M	6 / 172	3	11	11 / 100	Y
Total	482 / 1069	48.7	52.5	546 / 1040	Total

7.4.3.2 Patient characteristics

Overall, intervention and control units were balanced with respect to patient characteristics except for, as in the case note review, a higher proportion of medical abortions in the intervention arm (Table 7.14). It had been intended to compare Carstairs indices using responses to an item about postcode sector in the questionnaire. However, this was not possible as responses to this item were frequently found to be unsuitable for analysis.

Table 7.14. Baseline characteristics of questionnaire respondents.

Baseline characteristic (weighted mean)	Intervention Mean per cluster (SD)	Control Mean per cluster (SD)
Patient age at time of referral	24.4 (7.63)	24.4 (7.67)
Estimated gestation at date of abortion	8.4 (3.22)	9.1 (3.04)
Method of abortion (proportion having medical abortions)	53.5	48.5
Mean number of cases per cluster	37.1 (36.1)	45 (59.9)

7.4.3.3 Compliance with guideline recommendations

No significant differences between the intervention and control groups were observed with respect to the organisation of services, abortion procedures or aftercare (Table 7.15). However, significantly fewer women in the intervention group recalled having been counselled adequately about the complications and possible sequelae of abortion (OR for summary score 0.45, 95% CI

0.25 to 0.80). Out of the possible complications, intervention group women recalled failure of the abortion method (OR 0.59, 95% CI 0.33 to 0.95) and pelvic infection (OR 0.53, 95% CI 0.34 to 0.82) significantly less often.

Table 7.15. Compliance with recommendations as measured by patient survey.

Recommendation (total number of eligible cases)	Percentage intervention median (IQR) compliance	Percentage control median (IQR) compliance	Odds ratio (95% CIs)
Organisation of services			
Ideally, all women are offered an assessment appointment within five days of referral (n=965)	25.0 (13.5, 34.7)	25.0 (11.8, 38.2)	1.0 (0.49, 2.05)
As a minimum standard, all women are offered an assessment appointment within two weeks of referral (n=965)	96.0 (89.3, 99.1)	99.1 (82.6, 100)	1.06 (0.40, 3.00)
Ideally, all women can undergo the abortion within seven days of the decision to proceed being agreed (n=959)	85.0 (72.1, 84.7)	78.5 (71.4, 97.7)	1.73 (0.81, 3.67)
As a minimum standard, all women can undergo the abortion within two weeks of the decision to proceed being agreed (n=959)	100 (96.0, 100)	95.9 (92.3, 100)	1.85 (1.01, 3.56)
As a minimum standard, no individual woman need wait longer than three weeks from initial referral to the time of abortion (n=912)	84.0 (78.1, 95.0)	85.2 (75.3, 98.1)	1.60 (0.63, 4.15)
Information for women			
Verbal advice must be supported by accurate, impartial printed information which the woman considering abortion can understand and may take away and read before the procedure (n=1012)	78.8 (58.3, 84.9)	64.6 (42.3, 90.5)	1.45 (0.64, 3.32)
Information for women and professionals should emphasise duty of confidentiality (n=1012)	92.4 (88.9, 100)	96.1 (87.7, 100)	1.11 (0.44, 1.99)
Professionals providing abortion services should possess accurate knowledge about possible complications and sequelae of abortion			
Possible complications mentioned to women (n=1006)	85.2 (69.5, 96.4)	89.0 (80.8 , 92.8)	0.46 (0.3, 0.69)
Excessive bleeding following the abortion (haemorrhage, n=972)	69.9 (61.5, 74.5)	75.5 (62.5, 83.2)	0.76 (0.52, 1.12)
Damage to the uterus, or womb, requiring a more major operation (uterine perforation; only relevant to surgical abortions; n=438)	55.0 (25.1, 66.7)	68.2 (18.8, 88.8)	0.55 (0.24, 1.25)
Failure of the abortion method (and need for another abortion procedure; n=977)	50.0 (32.1, 59.0)	63.6 (42.3, 76.5)	0.59 (0.33, 0.95)
Pelvic infection (n=978)	51.4 (36.0, 66.2)	68.5 (45.9, 80.1)	0.53 (0.34, 0.82)
Summary score (for above five questions; n=906)	22.7 (8.7, 35.4)	45.7 (9.8, 59.0)	0.45 (0.25, 0.80)
Abortion procedures			
Ideally, abortion services must be able to offer a choice of recommended procedures for relevant gestation bands (n=826)	53.8 (23.6, 69.5)	50.0 (21.8, 75.9)	1.13 (0.47, 2.69)
After care			
After an abortion, women must be given a written account of the symptoms they may experience and a list of those that would make an urgent medical consultation necessary (n=973)	67.5 (46.8, 82.5)	77.2 (52.9, 80.0)	0.67 (0.36, 1.25)
A follow-up appointment (either within the abortion service or with the referring clinician) within two weeks of the procedure should be offered to each patient following abortion (n=1029)	18.2 (15.8, 30.3)	14.3 (1.9, 25.5)	1.36 (0.77, 2.85)
Before she is discharged following abortion, future contraception should have been discussed with each patient (n=981)	98.3 (94.3, 100)	100 (99.0, 100)	1.09 (0.39, 2.34)
Offer of contraceptive supplies if required; chosen method of contraception initiated immediately following abortion (n=972)	88.2 (79.2, 100)	93.8 (80.0, 100)	0.94 (0.29, 2.48)
Sterilisation can safely be performed at time of induced abortion. However combined procedures are associated with higher rates of failure and regret (n=1029)	100 (98.7, 100)	100 (100, 100)	1.53 (0.35, 5.53)
It is safe and effective to insert an IUCD for contraceptive use immediately following induced abortion (n=1029)	12.5 (1.8, 15.9)	6.5 (0, 34.5)	0.66 (0.27, 1.57)

7.4.3.4 Satisfaction with care received

There were no significant differences with respect to satisfaction received (Table 7.16) or other outcomes of counselling (Table 7.17) between the intervention and control groups.

Table 7.16. Satisfaction with care received (lower scores indicate stronger agreement with statements on a 1 to 5 scale)

Recommendation (total number of eligible cases)	**Weighted intervention mean (SD)**	**Weighted control mean (SD)**	**Difference* (95% CIs)**
Staff competency			
The clinical care I received was excellent (n=1013)	1.6 (0.7)	1.7 (0.7)	-0.44 (-0.16, 0.07)
My confidentiality was protected (n=1012)	1.6 (0.7)	1.6 (0.7)	0.02 (-0.08, 0.13)
The staff treated me with respect (n=1020)	1.5 (0.6)	1.5 (0.6)	-0.04 (-0.14, 0.07)
The staff were professional and thorough (n=1020)	1.5 (0.6)	1.5 (0.5)	0.02 (-0.08, 0.11)
Summary score (n=1005)	1.5 (0.5)	1.6 (0.5)	-0.01 (-0.09, 0.08)
The counselling process			
There was too much emotional talk (n=968)	3.8 (0.8)	3.8 (0.8)	-0.01 (-0.19, 0.18)
There was too much medical talk (n=969)	3.8 (0.7)	3.8 (0.7)	-0.01 (-0.14, 1.29)
The staff asked too many questions (n=975)	4.0 (0.7)	4.0 (0.7)	0.01 (-0.12, 0.14)
Summary score (n=963)	3.9 (0.6)	3.9 (0.6)	0.13 (-0.49, 0.76)
Staff sensitivity			
The staff treated me as a whole person (n=1016)	1.5 (0.6)	1.5 (0.6)	-0.05 (-0.16, 0.06)
The staff weren't afraid to discuss emotional issues (n=1010)	2.1 (0.9)	2.2 (0.8)	-0.10 (-0.16, 0.14)
Summary score (n=1008)	1.8 (0.6)	1.8 (0.6)	-0.03 (-0.15, 0.08)
Global satisfaction			
There are some things about the medical care I received that could be better (n=1004)	3.7 (1.0)	3.6 (1.0)	0.01 (-0.13, 0.16)

*Differences may differ slightly from those between intervention and control means in preceding columns because of adjustment for clustering in GEE

Table 7.17. Other outcomes following counselling.

	Percentage intervention median (IQR) compliance	Percentage Control median (IQR) Compliance	Odds ratio (95% CIs)
During your clinic appointments, did you have enough time and help in reaching your decision to have an abortion? (n=984)	96.8 (92.5, 100)	96.3 (93.7, 100)	0.72 (0.33, 1.24)
Do you feel now that your decision was right for you? (n=976)	100 (95.9, 100)	100 (97.6, 100)	1.13 (0.59, 2.56)

7.4.4 Economic evaluation

Costs. The total cost of the intervention was £26,875 for 13 units, an average (mean) cost per unit of £2067. Table 7.18 presents a summary of these costs whilst Appendix 7I details the full costing. The largest component of this cost was incurred at the audit and feedback stage, estimated at £1026 per unit.

Since the ImpACT implementation strategy involved numerous meetings for training, data collection and action planning, staff time costs were anticipated to comprise the largest component of costs. All grades of staff involved in the provision of the abortion service in each of the intervention units were involved at each stage. Over half of the total cost for the outreach educational meetings was related to staff attendance at the meetings (£4228 out of a total of £8041).

Table 7.18. Estimated costs of intervention.

Component	Total cost (£)	Mean cost per gynaecology unit (£)
Audit and feedback	13341	1026
Identification of barriers	4579	352
Educational meetings	8041	619
Review of structured case records	881	68
Promotion of patient information booklet	31	2
Total	26,875	2067

Primary outcomes. The lack of statistically significant differences in primary outcomes attributable to the intervention meant that a cost effectiveness analysis was not justified. Although the study was limited by the relatively small total number of hospitals, the magnitude of any differences was small from a substantive point.

Secondary outcomes. Similarly, the insignificant differences in secondary outcomes (from both statistical and substantive perspectives) meant that cost effectiveness analysis of these outcomes was not warranted.

The numbers of control and intervention units reporting any action taken on the key recommendations, along with a description of these changes (when stated by the unit) is presented in Table 7.19. In total, the intervention and control units reported similar rates of action for the key guideline recommendations, though the types of actions varied.

Table 7.19. Action taken on key recommendations: number of units reporting changes and description of change.

Recommendation	**Control**	**Examples of changes / comments**	**Intervention**	**Examples of changes / comments**
Appointment within five days	2	Referral system modified to routinely faxed abortion requests; all women now seen by one consultant	4	Overflow clinic established. Reminder to practices of 'hotline' for referrals; extra patient per clinic (with increased ward throughput).
Cervical screening history	1	Standard proforma designed and introduced for all patients	2	Now routinely record smear status if over 20 years
Antibiotic prophylaxis and / or screening	2	Routine antibiotic use since October 2001; standardised prescription chart now used.	3	Standardisation of local policy - all women now screened *and* all offered antibiotic prophylaxis; Standardisation of protocol - all patients now receive doxycycline (plus azithromycin if positive for *chlamydia*); change of antibiotic to universal use of azithromycin.
Use of misoprostol	2	Misoprostol introduced as part of a clinical study; misoprostol used in medical abortions as standard; with similar change planned for surgical abortions.	2	Standardisation of policy towards more consistent use of misoprostol; now use misoprostol for 1st and 2nd trimester medical abortions
Contraceptive supplies	2	Proforma sets out explicit plan.	2	Routine recording in nursing and medical notes of contraception offer and provision; oral contraception now prescribed at assessment clinic (named patient basis).
Other	9	Better written information for patients; increased use of medical abortions; integrated care pathway introduced; early medical abortion service about to be introduced; medical abortion now offered at 9-12 weeks gestation	6	Reduction in senior nursing input Development of patient leaflet Development of Integrated Care Pathway.

Several units provided details of staff time in changing clinical policy and implications for resource use as a consequence of a change in policy (e.g. use of antibiotics or contraceptives).

Unfortunately, the information was not always sufficiently detailed or specific to enable a reliable estimate of the costs of these changes to be made. However, in order to illustrate the nature and extent of any effects on resource use, quoted estimates of staff time and other resources involved in policy changes are listed in Table 7.20. Some changes in resource use could have occurred. Where units changed their policy on antibiotic prescribing there would be corresponding changes in drug costs. Similarly, extra provision of contraceptives would have incurred additional prescribing costs. The use of misoprostol in place of gemeprost would have reduced costs since the latter is more expensive.

Table 7.20. Reported details of the staff time to effect any policy change and any implications for resource use as a consequence of changes in policy.

	Intervention units	*Control units*
Examples of staff time involved in policy discussions and changes	Additional session of Trust grade doctor time to operate an extra overflow clinic. One hour for 2 consultants in agreeing changes to policies for recording smear status, antibiotic prophylaxis policy, misoprostol use, and policy on the provision of contraceptives. Meetings about change to prostaglandin use with pharmacists and consultants plus briefing of nursing staff estimated at 2 hours for one consultant and 1 hour for a senior pharmacist. 48 hours of consultant time (and unspecified head pharmacists time) negotiating change in contraception prescribing policy with pharmacist. 3 hours of staff nurse time to develop a patient leaflet. 5 hours for both a consultant and staff nurse for development of integrated care pathway.	Development of standard proforma for cervical smear status required 10 hours of consultant time. Negotiation for change to use of misoprostol took 6 hours of consultant grade time. Audit project on discharge documentation for contraception provision required 4 hours of senior house officer grade time. Improvements in written patient information required 1 hours of consultant time plus 4 hours of staff nurse time. Higher proportion of medical abortions increased demand on nursing time. Change to misoprostol required 8 hours of consultant time to negotiate. Change to routine antibiotic use required 4 hours of consultant grade time for paper submitted to clinical governance committee. Integrated care pathway involved a wide range of staff in a steering group for monthly meetings of 1 – 1 1/2 hours over 6 months.
Perceived costs / benefits to other services of the processes or changes	Perception of reduced delays in referrals from some practices as a result of reminder about hotline for referrals. Increased awareness of recording issues and increased confidence of day care staff.	Routinely faxed referrals made appointments easier to arrange. Earlier discharge freed up bed space and helped to increase throughput. Big reduction in waiting times as a result of additional clinic session and use of a single lead consultant on one afternoon with all women now seen within 5 days. Standardised prescription chart saves time writing up prescriptions. Medical abortions offered at 9-12 weeks reduced theatre time.

7.5 Discussion

7.5.1 Main findings

A tailored, multi-faceted strategy, delivered under the auspices of a national clinical effectiveness programme, to promote implementation of a clinical guideline had no effect on the quality of induced abortion care. Moreover, there was no evidence that the strategy reduced variations in compliance among intervention units compared with controls.

According to the post-intervention case note review, overall median compliance was 100% for two of the key recommendations (antibiotic prophylaxis or screening for lower genital tract organisms and misoprostol as a cost-effective alternative to gemeprost), indicating little scope for improvement ('ceiling effects'). Compliance remained poorest for the provision of an appointment with a gynaecologist within five days of referral (intervention 35.5%; control 40.5%). The lack of effects for the other two key outcomes (ascertainment of cervical cytology history and the offer of contraceptive supplies prior to discharge) were also disappointing.

The patient survey produced a satisfactory overall response rate, although unexpectedly lower in the intervention arm (45.1%) than in the control arm (52.5%). Significantly fewer women in the intervention group recalled having been counselled about the complications and possible sequelae of abortion (OR 0.45, 95% CI 0.25 to 0.80). No other significant differences between the intervention and control groups were observed with respect to compliance with recommendations or satisfaction with care received.

The average cost of the intervention per gynaecology unit was £2067, with the audit and feedback component accounting for half of this cost. The lack of any significant differences in primary outcomes meant that a cost-effectiveness analysis was not justified. Both the intervention units and the control units reported some changes in abortion policy. It was not possible, given the information available, to readily identify whether any changes in the intervention units occurred as a direct result of the intervention. It is conceivable that there were some changes in efficiency of provision of abortion services that were not reflected in the primary or secondary outcome measures. There was no other evidence that any efficiency gains were necessarily greater in intervention units than in control units.

7.5.2 Strengths and weaknesses of study design

The ImpACT implementation strategy and its evaluation had several important strengths. Firstly, the guideline recommendations disseminated were developed using a rigorous methodology, benefiting from a major input from groups representing patient interests. Secondly, the study

employed a strategy tailored according to systematically identified needs and barriers. The design and content of the interventions were based upon a theory of behavioural change, thereby enhancing the generalisability of findings. Thirdly, ImpACT used a rigorous design achieving both greater validity than much previous implementation research and greater generalisability to UK secondary care settings. Fourthly, an economic evaluation was included, frequently absent from previous research despite the major opportunity costs of clinical effectiveness initiatives.

The quality of the study design can be assessed according to the Methodological Quality Criteria for randomised evaluations set out by the Cochrane Collaboration Effective Practice and Organisation of Care (EPOC) Group (278).

Concealment of allocation. For cluster randomised trials, the unit of allocation and the randomisation process should be explicitly described. Gynaecology units comprised the unit of allocation and randomisation was performed using a computer programme.

Follow up of professionals. To protect against exclusion bias, outcome measures should be available for at least 80% of professionals randomised. No cases were identified nor patient questionnaires returned for one small unit allocated to the control arm. One consultant in the intervention arm refused permission for access to patient case notes. Post-intervention data were available for the patients of all consultant gynaecologists providing abortion care in Scotland during the study period (except one from an intervention unit who refused permission to access case notes).

Follow up of patients or episodes of care. A follow up of at least 80% of patients randomised is judged necessary to protect against exclusion bias. For the larger units, random quota sampling was used to derive a representative sample of patients. In the smaller units, all cases were included if 75 or less eligible cases were identified for the post-intervention period. The cases were identified using ward and day care diaries as this was considered the most comprehensive method of case identification. A small number of case notes were missing in some units, requiring replacement by other randomly selected cases to make up the quota of 75. The proportion of missing case notes did not approach 20% in any unit.

The overall response rate to the patient survey was 49%. Although considerably below the 80% threshold, this represents a satisfactory response rate compared with other surveys of this client group (263;264). However, the overall response rate masks marked variations in response rates among individual gynaecology units, ranging from 3 to 98%. Therefore, women responding in units with lower response rates may have systematically differed from those in other units (e.g.

feel more satisfied with care received). Assuming that the case note review was generally representative of all women receiving abortion care in Scotland, there was evidence that respondents to the questionnaire were similarly representative. The mean age of the women was similar to that of the case note review. The mean gestation at the time of abortion was also consistent with the overall mean for the case note review (8.8 weeks). It remains possible that women responding to the questionnaire were more, or less, satisfied with their care than those in the reference population.

Whilst the external validity of the survey may be acceptable, the other key issue within the context of a randomised trial concerns internal validity and the possibility of response bias, i.e. differences in the characteristics of respondents between the intervention and control arms. The response rate was 7% higher in the control arm. This was unexpected because greater awareness of the trial, and hence improved distribution of the questionnaire, was anticipated in the intervention arm. Yet there were no differences in the baseline characteristics between the intervention and control arms, except for the proportion undergoing medical abortions. This suggests that the women in the two arms were broadly similar, reducing the likelihood of significant response bias.

Blinded assessment of primary outcomes. The assessment of primary outcomes should be blinded or outcome measures are objective (e.g. length of stay, drug levels). Data collection for the case note review was not blinded but the outcomes were objective processes of care. During data checking, unexpected low levels of compliance were queried (e.g. use of antibiotic prophylaxis or screening). It is conceivable that feedback from the intervention units during the educational meetings improved ascertainment of outcomes when some data items were subsequently reviewed and corrected. However, efforts were also made to validate low compliance for key recommendations in the control units. Furthermore, clinical policies were confirmed during the interviews with both intervention and control lead gynaecologists at the end of the follow up period.

Baseline measurement. Performance or patient outcomes should be measured prior to the intervention, and no substantial differences should be present across study groups. Pre-intervention performance was measured, mainly to inform the matched randomisation and provide data for the audit and feedback component. The numbers of cases in individual clusters were insufficient to allow reliable comparisons to be made before and after the intervention. Several minor pre-intervention imbalances were present. Notably, the use of antibiotic prophylaxis or screening was higher in the intervention arm review (Table 6). However,

regression modelling which accounted for pre-intervention compliance levels demonstrated little impact on the final outcomes compared with an unadjusted analysis.

Reliable primary outcome measures. There should be good inter-rater agreement or the outcome assessment should be objective. This was also met as discussed above.

Compliance with ten recommendations was assessed by both the (post-intervention) case note review and patient survey. This provided an opportunity to compare findings related to the use of either method (Table 7.21). The overall medians were similar for seven out of ten recommendations. This comparison suggests that the case note review over-estimated compliance for the offer of an assessment appointment. The differences in the other two recommendations related to after care probably demonstrate lack of documentation in the case notes (although actual documentation itself represents a valid outcome). These differences are unlikely to reduce the internal validity of the study.

Table 7.21. Comparison of results from different data sources used to measure compliance with guideline recommendations.

Recommendation	Overall % median compliance		Comments
	Case notes	Patient survey	
Organisation of services			
Ideally, all women are offered an assessment appointment within five days of referral	39.1	25.0	Case note review relied upon documented date on referral letter – may under-estimate interval and hence over-estimate compliance. Survey asked women to recall time interval between first contact (for referral) and first hospital or specialist appointment – may represent imprecise estimate
As a minimum standard, all women are offered an assessment appointment within two weeks of referral	94.6	96.6	
Ideally, all women can undergo the abortion within seven days of the decision to proceed being agreed	80.0	80.0	
As a minimum standard, all women can undergo the abortion within two weeks of the decision to proceed being agreed	96.0	97.4	
As a minimum standard, no individual woman need wait longer than three weeks from her initial referral to the time of her abortion	93.1	84.6	
After care			
A follow-up appointment (either within the abortion service or with the referring clinician) within two weeks of the procedure should be offered to each patient following abortion	8.0	17.4	Case note review assessed actual documentation of an appointment date – hence under-estimating offers Patient survey asked whether follow-up appointment had been arranged. Refusal to accept a further appointment was counted as non-compliance to enhance comparability
Before she is discharged following abortion, future contraception should have been discussed with each patient	98.0	100	
Contraceptive supplies should have been offered if required. The chosen method of contraception should be initiated immediately following abortion	73.9	91.8	Case note review and patient survey asked similar questions – with former relying upon documented evidence of availability or supply.
Sterilisation can safely be performed at the time of induced abortion. However combined procedures are associated with higher rates of failure and of regret	100	100	
It is safe and effective to insert an IUCD for contraceptive use immediately following induced abortion	9.3	8.1	

Protection against contamination. Allocation to study group should be by community, institution or practice and it should be unlikely that the control group received the intervention. The risk of contamination among units was recognised, especially in view of the concomitant NHS Trust mergers. Discussions with relevant clinical directors had suggested that shared

clinical effectiveness activities were minimal during the intervention and follow-up periods. Furthermore, during the intervention phase, measures were taken to avoid contamination, e.g. avoidance of any joint educational meetings between Trusts.

The study took place within the broader context of a national clinical effectiveness programme. The existence of the programme and knowledge of the trial among clinicians may have exerted non-specific Hawthorne effects that improved performance in the control units. However, there were no consistent trends towards improved median compliance pre- to post-intervention across the recommendations in the control arm, most notably for the main outcomes (Table 7.22). The ascertainment of cervical cytology status did improve across both intervention and control arms but was most likely to be related to the growing use of structured case records. The larger increase in compliance for the offer of contraceptive supplies probably represents a case of regression to the mean, especially given that the median intervention unit compliance actually fell from 80.5% to 73.9%.

Table 7.22. Median unit pre- and post-intervention compliance with five key outcome recommendations in the control arm.

Recommendation	Median unit pre-intervention compliance (%)	Median unit post-intervention compliance (%)	Change (%)
Appointment with a gynaecologist within five days of referral	41.1	36.0	-5.1
Ascertainment of cervical cytology history	61.4	69.6	8.2
Antibiotic prophylaxis or screening for lower genital tract organisms	97	96.5	-0.5
Misoprostol cost-effective alternative to gemeprost	98.6	100	1.4
Offer of contraceptive supplies if required prior to discharge	58.6	78.3	19.7

In conclusion, the study design satisfied most of the Methodological Quality Criteria for randomised evaluations. Nevertheless, as discussed below (7.5.5), the power of the study could have been enhanced by attaining more precise estimates of pre-intervention compliance.

7.5.3 Possible explanations for the main findings

This study indicated that the multi-faceted strategy to improve abortion care had no beneficial effect. Possible explanations for this result relate to the study methodology and timing, and the uptake, ownership and selection of the interventions.

Methodology. Other studies evaluating multi-faceted strategies that have included educational outreach and audit and feedback have found modest to moderate effects (103). Some of these evaluations involved the use of non-randomised designs or poorer quality methods, often associated with larger effect sizes (279;280). The use of a robust methodology could simply suggest that such a multi-faceted strategy was ineffective but other reasons for this negative finding, including other aspects of the study methods, merit consideration.

Two factors related to the outcomes may have contributed to the failure to demonstrate any effect. Firstly, the relatively small number of clusters and the coincident failure of the matched randomisation resulted in reduced statistical power. However, no trends were observed in favour of the intervention, suggesting that a more highly powered study would not have detected any consistent and significant differences. Secondly, the post-intervention outcomes measured performance within three months of the completion of the main intervention (the outreach educational meetings). As some of the key recommendations required changes in clinical policy or organisation of services, it is possible that there was insufficient time for such changes to work through to the actual delivery of care.

Two findings make this latter explanation less likely. There was little difference between the control and intervention arms in the numbers of lead gynaecologists reporting any actions taken over the key recommendations. And no differences were observed for recommendations where greater awareness might have led, at least in part, to changes in practice (such as documenting the history of cervical cytology). There was limited evidence of an intervention effect related to one of the secondary outcomes: a follow-up appointment within two weeks of the procedure should be offered to each patient following abortion. There was resistance to the universal routine offer of an appointment within this time period. But most participants in the outreach educational meetings agreed that documenting follow-up arrangements offered within any time scale represented good medico-legal practice and enhanced communications with other sectors (e.g. primary care). Weighted mean intervention compliance with documentation of follow-up arrangements over any period of time was 75.8% (SD 24.8) versus 48.4% (SD 25.2) in the control group, a difference of 27.4% (95% CI 6.5 to 48.2; OR 3.4, 95% CI 1.4 to 8.5). This suggests that participants made changes that were relatively straightforward to implement and (perhaps) more readily accepted as representing good professional practice.

Overall, insufficient power and timing of the outcome measurements are unlikely to explain the absence of an intervention effect.

Timing of study. The study took place approximately ten years following the Gynaecology Audit Project in Scotland (GAPS) (149). Despite improvements following GAPS, inappropriate variations in care had remained. The RCOG guideline was developed in response to such problems and was published a year before the trial intervention started. The pre-intervention case note review demonstrated that compliance for one of the key recommendations, antibiotic prophylaxis and screening, had substantially improved since GAPS. Pre-intervention compliance was also high for another key recommendation, the use of misoprostol as a cost-effective alternative to gemeprost. Such 'ceiling effects' may explain the lack of effect demonstrated in relation to these two recommendations. Similar problems have been encountered with evaluations elsewhere (247;281). Indeed, an audit of the implementation of clinical practices supported by Cochrane Reviews in maternity care demonstrated a marked improvement, leading the authors to suggest that the dissemination of high quality research does change practice, providing time is allowed for the necessary accumulation of consensus (282).

Pre-intervention measures of compliance suggested that scope for improvement still existed in relation to other recommendations (e.g. offer of an appointment within five days). However, the implementation of such recommendations may have been more difficult as they required more complex organisational changes or wider attitudinal shifts.

Uptake of intervention. All intervention units accepted the intervention package. However, the intervention and control units reported similar rates of action for the key guideline recommendations, though the types of actions varied. Actions reported by the intervention units were subjectively perceived to have a greater degree of focus than the actions undertaken by control units, though any differences were not ultimately reflected in the primary or secondary outcomes.

Ownership. The trial intervention comprised a multi-faceted strategy deliverable within the context of a national clinical effectiveness programme. This approach offered the potential advantages of standardisation of the intervention and enhanced credibility of its association with a credible professional network. However, as most of the planning and organisation of the intervention were centralised, ownership by clinicians might have been lower compared with locally led efforts to improve care. The average amount of time lead gynaecologists spent directly on delivery of the intervention – although not insignificant – amounted to an average of less than four hours. Therefore, the intervention might not have been sufficiently focused nor locally owned to promote change. Elsewhere, the relatively small impact of a tailored complex intervention has also been attributed to its relatively passive nature (209).

The lead researcher (i.e. the author) was experienced in teaching evidence-based medicine using interactive styles and mainly led the outreach educational meetings. Presentations delivered by a peer (i.e. a gynaecologist) could have been perceived as being more credible although such an approach did not work elsewhere (247). An alternative approach would be to ask local clinicians to present audit findings themselves. This would possibly engender greater ownership of and responsibility for the audit findings and is planned for future SPCERH audit work of this nature.

Gynaecology units were asked to set at least two or three targets following the feedback meetings, preferably including action on one of the five key recommendations. The guideline itself contains 57 recommendations. The potential advantage of such a wide ranging audit is that it allows units to identify local priorities requiring further action. It is possible that action taken locally in response to the guideline was 'diluted' across this range of recommendations – and therefore not detected among any of the outcome measures. Specifying and focusing implementation on a smaller number of recommendations might have provided gynaecology units and the study with a more realistic target.

Appropriateness of intervention to identified barriers. The use of a systematic and combined approach to identifying barriers makes it unlikely that the ImpACT strategy failed because of a wrong diagnostic analysis. The main weaknesses probably concerned the selection or tailoring of interventions (Chapter 6.6.4). Work on developing the intervention strategy suggested that a 'ceiling' had been reached on motivating most staff involved in the delivery of abortion care to follow the recommendations. Therefore, components of the strategy that aimed to increase motivation were unlikely to be effective. Interventions targeting wider aspects of the organisation might have been more appropriate and effective.

In summary, there are several plausible explanations for the lack of an intervention effect. Those considered most likely to have contributed include the timing of the study (and associated 'ceiling effects'), and the intensity and appropriateness of the intervention.

7.5.4 Other findings

Information on complications and sequelae. Significantly fewer women in the intervention group recalled having been counselled about the complications and sequelae of abortion. There are three possible explanations for this apparently harmful effect of the intervention. The first is that it represents a chance finding, partly related to multiple significance testing. This seems unlikely given the magnitudes of the differences between the intervention and control groups and, more importantly, the finding that outcomes were significantly worse for three out of the five items contributing to the summary score. The second explanation is that this finding

represents a real (side) effect of the intervention. However, the likely mechanism is not certain. Clinicians in intervention units may have paid greater attention to other aspects of abortion care (e.g. the five main outcome recommendations) at the cost of improving information for women. Yet, there were no reports from control units of specific efforts to improve information and, overall, there were no differences in reported actions taken to implement the guideline between intervention and control units. The third explanation relates to potential pre-intervention imbalances. There are no data on patient information prior to the intervention but this remains the most likely explanation given pre-intervention imbalances with respect to other outcomes and the lack of evidence to support the alternative causes.

Potential sub-group effects. No effect of the ImpACT strategy was found across gynaecology units exhibiting a range of compliance. It could be hypothesized that the strategy could have exerted an intervention effect among units with lower pre-intervention compliance. An *a priori* sub-group analysis of this nature was not considered in the design of the trial but might be of value in future studies.

There are three reasons why the detection of any sub-group effect would have been unlikely in ImpACT. Firstly, on exploration of the process and outcome data, there was no clear link between gynaecology units' reported actions to implement the recommendations and improvement in compliance. Secondly, there was no indication of consistently improved compliance pre- to post-intervention across the primary and the secondary outcomes. Thirdly, the analysis of changes in compliance pre- to post-intervention would be hindered by the unreliability of the pre-intervention estimates of compliance and the small number of gynaecology units available for such an analysis. These factors reduce the probability of finding a sub-group effect but do not in themselves disprove the hypothesis of a sub-group effect.

A small *post-hoc* exploration of the data was undertaken for one of the key recommendations for which there was evidence of an overall improvement in pre-post compliance: the offer of contraception at discharge. Eight intervention units had pre-intervention compliance below 70% compared with four control units. Compliance improved by 15% or more for four out of eight intervention units compared with one out of four controls. This could be interpreted as a chance effect or result of selection bias (since these gynaecology units may have differed systematically from the whole study sample). Regression to the mean is likely to have occurred but such effects should have been evenly distributed between intervention and control units. This *post-hoc* exploration provides insufficient evidence to support a sub-group effect. Furthermore, an alternative *post-hoc* analysis exploring detrimental effects (i.e. reductions in unit compliance

greater than 20%) would have demonstrated reductions in two intervention units compared to none of the controls.

7.5.5 Implications for clinical practice and policy

This study indicated that a tailored, multi-faceted strategy to promote adherence to the RCOG clinical guideline on induced abortion care, delivered within the context of a national clinical effectiveness, had no impact on the quality of care. This finding is context specific. It would be erroneous to conclude that tailored, multi-faceted interventions (involving educational outreach and audit and feedback) will be universally ineffective. Contextual modifiers, such as timing of the study, may have reduced the potential for the ImpACT strategy to have any effect.

There is evidence that the interventions selected were inappropriately targeted. In the case of ImpACT, the interventions were tailored in the light of known barriers, but the time scale to modify the interventions was short and the choice of interventions was limited. Those developing other initiatives to promote adherence to clinical guidelines should consider protecting more time for the development of implementation strategies and build a broader armoury of interventions. The continuing dilemma, given the limitations of the current evidence base, is what interventions are most likely to be effective (103)? There are no universal answers to this; no one intervention will be consistently effective across all contexts. The selection of any intervention should be based upon rigorous evidence of its effectiveness, cost considerations, feasibility and the nature of identified barriers and facilitators.

The costs of the strategy at national and local levels are of interest to policy-makers. The average cost of the intervention per gynaecology unit was £2067, with the audit and feedback component accounting for half of this cost. The organisation of activities, such as the audit, at a national level centralised costs and probably would have been less expensive compared with the organisation of similar activities locally across 26 gynaecology units. Data collected on local activities outside of the main interventions (Table 7.20) illustrated the hidden but not insubstantial costs of making even modest changes in clinical policy, e.g. time spent negotiating changes in drug regimens or availability (283). The hypothetical trade-off is that locally-led and owned activities might have been more effective in changing practice.

7.5.6 Recommendations for further research

ImpACT has highlighted lessons on the statistical design and analysis of cluster randomised trials, the selection of clinical topics, and the use of theory in designing interventions.

Statistical design and analysis. The importance of statistical issues in the design of cluster randomised trials was highlighted in the design and analysis of this study. In ImpACT, the patients identified at each time pre- and post-intervention period were different; hence this trial used a repeated cross-sectional design. This differs from a cohort design whereby the same patients are assessed both pre- and post-intervention. Pre-intervention data were collected to inform matched randomisation and thus increase power. In the event, the cluster sizes (of up to 50 cases) in the pre-intervention period were too small to allow sufficiently precise estimates of compliance. The imprecise estimates of pre-intervention performance led to low correlation between pre- and post-intervention performance. Hence, incorporation of pre-intervention performance may not improve the precision of the intervention effect (J Mollison, personal communication)(271). Given several pre-intervention imbalances in ImpACT outcomes, a secondary analysis was performed incorporating pre-intervention compliance. This approach subsequently had a negligible impact on the results compared with the analysis of post-intervention outcomes alone. Therefore, the latter analysis was used.

'Careful stratification' of clusters prior to randomisation represents one option to prevent such difficulties in the interpretation of repeated cross-sectional designs (271). Given the failure of this approach within ImpACT, it is recommended that stratification is based upon sufficiently large pre-intervention samples to allow precise estimation of pre-intervention performance or that larger post-intervention samples are obtained.

The other factors with important influences on statistical power were the number of clusters and levels of compliance. Firstly, the number of gynaecology units in Scotland was limited but, given the national boundaries of SPCERH, it was not feasible to recruit further units from elsewhere. Had more units been available, recruiting more units would have represented a more efficient means of increasing statistical power than sampling more patients per cluster (269). Secondly, high levels of compliance with several recommendations made the analysis more problematic. Lessons learned from this are discussed next.

The selection of clinical topics. The development of clinical guidelines is usually prompted or justified by demonstrated inappropriate variations in the quality of care. The RCOG guideline had been developed in response to such problems in abortion care, in part demonstrated by a previous Scottish audit (149). Although the ImpACT analysis showed continuing deficits in access to services and after-care, quality of care had already markedly improved for recommendations probably more amenable to change. Greater scrutiny of the scope for improving practice is needed when selecting guideline topics for evaluation and appropriate interventions. Unfortunately, costly pre-study data collection may be required to assess the

extent of inappropriate care. This barrier can potentially be circumnavigated by using a range of other data sources, such as routine NHS data and surveys of professional practice, whilst allowing for their limited validity.

The use of behavioural theory. Strategies that aim to change professional and organisational behaviour represent complex interventions. The MRC framework for the development and evaluation of complex interventions recognises the need to establish the theoretical bases of interventions and undertake exploratory studies to choose and refine interventions (207). This enables interventions to be optimised for evaluation in definitive trials and can improve understanding of the generalisability of subsequent findings. As in ImpACT, theories from behavioural sciences are now being used to investigate professional and organisational practice. Greater use of theory may help explain why interventions work in some contexts but not others. The overall aim of such work is to develop a scientific basis for selecting and evaluating an approach to improve professional and organisational practice given specific barriers and circumstances.

7.6 Conclusion

This cluster randomised trial tested the effectiveness of a tailored package delivered under the auspices of a national clinical effectiveness programme comprising audit and feedback, educational meetings, dissemination of structured case records, and promotion of a patient information booklet. The strategy produced no significant improvements in the quality of care with respect to the primary and secondary outcomes. There was no evidence that the ImpACT strategy reduced variations in compliance among intervention units compared with controls. The lack of significant differences in primary outcomes meant that a cost-effectiveness analysis was not justified. The mean cost of the intervention per gynaecology unit was £2067, with the audit and feedback component accounting for half of this cost. There was no evidence that intervention units planned or made more changes to service provision than control units.

The most likely explanations for the lack of an intervention effect include the timing of the study in relation to publication of the guideline (with associated 'ceiling effects'), and the intensity and appropriateness of the intervention.

Chapter 8

Application of a framework to appraise the validity of the study designs

8.1 Summary

This chapter sets out an assessment of the strengths and weaknesses of the six different studies presented within this thesis with respect to their validity, cost and relevance to the needs of the SPCERH programme. Four different types of validity were considered: statistical conclusion; internal; construct; and external.

The main threat to statistical conclusion validity comprised low statistical power in the interrupted time series analysis and cluster randomised trial, increasing the potential for type II error. In contrast, multiple hypothesis testing in the uncontrolled before and after survey of obstetrician reported practice increased the likelihood of type I error. The analyses of four studies appropriately adjusted for clustering effects, thereby reducing the likelihood of type I errors.

Adding or improving control groups improved internal validity, progressively countering the potential biases of history, maturation, regression and selection effects. Although the cluster randomised trial emerged with the fewest threats to internal validity, the interpretation of the time series was only limited by the possibility (but not probability) of history and instrumentation effects.

The definition of study constructs and recognition of confounding represented key issues in determining construct validity and, hence, transferability of the research findings. The study constructs became more complex with increasing sophistication of both study designs and interventions. The failure to describe studies according to a common taxonomy contributes to confusion and uncertainty over the effectiveness of interventions to improve professional practice.

The studies were of moderate to high generalisability to secondary care professionals targeted by SPCERH activities. However, the absence of any observed effects in the time series analysis and cluster randomised trial does not necessarily mean that that none would be observed in different settings of if the interventions were to be varied.

The cost of the studies increased with growing complexity of design. All studies met the needs of SPCERH's work programme, particularly the development of clinical guidelines and monitoring standards through clinical audit, and the development of ways of implementing effective practice through research.

8.2 Introduction

The work described in this thesis drew upon a range of study designs, briefly described in Chapter 1.8.2 and summarised in Table 8.1. Each study design and its methods are associated with different factors that may strengthen or threaten validity. This section will consider the meaning of validity and threats to different types of validity, using the framework and definitions put forward by Shadish, Cook and Campbell (284;285).

Table 8.1. Summary of study objectives and designs.

Study objective (chapter)	Design
To determine which attributes of recommendations from a national audit project best explain the extent of their adoption into clinical practice (2)	Observational: Observations made before and after an intervention
To survey Scottish obstetricians and midwives to assess knowledge of key clinical recommendations from the Report on Confidential Enquiries into Maternal Deaths in the UK 1994-6 (3)	Uncontrolled after: Observations only made following an intervention
To survey Scottish obstetricians to evaluate the impact of four national clinical guidelines on self-reported practice (4)	Uncontrolled before and after: Observations are made in one group before and after an intervention
To conduct a simple interrupted time series analysis to evaluate the impact of a national clinical guideline on the management of women with mild, non-proteinuric hypertension (5)	Simple interrupted time series analysis: Multiple observations made before and after an intervention
To identify barriers to the implementation of a clinical guideline on women requesting induced abortion and tailor a strategy to improve care (6)	Cross-sectional: Observations made at one point in time
To evaluate the effectiveness of a strategy, delivered within a national clinical effectiveness programme, to improve implementation of a clinical guideline on women requesting induced abortion (7)	Two-arm cluster randomised controlled trial: Groups of participants randomly allocated to different interventions

8.3 Validity

Validity refers to the truth of an inference. The determination of validity entails judging to what extent relevant evidence supports that inference as being true or correct. Evidence is judged on the basis of both empirical research findings and the consistency of these findings with other sources of knowledge, including previous research findings and theories. The determination of validity is seldom absolute, especially in relation to a single study, and judgements are fundamentally subjective. Furthermore, as Shadish *et al* highlight, validity is a property of inferences and not of study designs or methods (284). For example, critical appraisals of randomised trials frequently reveal flaws in their conduct, such as differential loss to follow up.

In such circumstances, it may be erroneously concluded that an intervention is effective despite probable biased estimates of effect.

There are four types of validity: statistical conclusion; internal; construct; and external. The following sections provide definitions and descriptions of associated threats to validity (i.e. biases). This scheme will later be used as a framework to appraise the studies described in this thesis.

8.3.1 Statistical conclusion validity

Statistical conclusion validity refers to whether there is a true association between an intervention and outcome and, if so, the strength of that association. The inference may be incorrect in one of two ways. Firstly, it may be incorrectly concluded that there is an association where none exists (Type I error). Secondly, it may be incorrectly concluded there is no association where one does exist (Type II error). Table 8.2 summarises the main threats to statistical conclusion validity.

Table 8.2. Threats to statistical conclusion validity (based on reference (284)).

Threat	Description
Low statistical power	An insufficiently powered experiment may incorrectly conclude that the relationship between an intervention and outcome is not significant
Violated assumptions of statistical tests	Violations of statistical test assumptions can lead to either overestimating or underestimating the size and significance of an effect
Fishing and the error rate problem	Repeated tests for significant relationships, if uncorrected for the number of tests, can artifactually inflate statistical significance
Unreliability of measures	Measurement error weakens the relationship between two variables and strengthens or weakens the relationships among three or more variables
Restriction of range	Reduced range on a variable usually weakens the relationship between it and another variable
Unreliability of intervention implementation	If an intervention that is intended to be implemented in a standardised manner is implemented only partially for some respondents, effects may be underestimated compared with full implementation
Extraneous variance in the experimental setting	Some features of an experimental setting may inflate error, making detection of an effect more difficult
Heterogeneity of units	Increased variability on the outcome variable within conditions increases error variance, making detection of a relationship more difficult
Inaccurate effect size estimation	Some statistics systematically overestimate or underestimate the size of an effect

8.3.2 Internal validity

Internal validity refers to the validity of inferences made about whether an intervention causes an outcome. Such inferences are supported if the intervention clearly precedes the outcome, if a statistical association has been demonstrated, and if no other plausible explanations for the relationship exist. Table 8.3 summarises the main threats to internal validity.

Table 8.3. Threats to internal validity (based on reference (284)).

Threat	Description
Ambiguous temporal precedence	Lack of clarity about which variable occurred first may yield confusion about which variable is the cause and which is the effect
Selection	Systematic differences in types of units recruited to intervention and control groups
History	External events occurring between pre- and post-intervention measurements which also influence outcome
Maturation	Naturally occurring changes over time could be confused with an intervention effect
Regression	Experimental units selected on basis of extreme scores tend to give subsequent scores closer to the average, an occurrence that could be confused with an intervention effect
Attrition	Loss of experimental units to the intervention or to measurement which can produce artifactual effects if loss is systematic
Testing	Administration of baseline measurement may alter response to subsequent measures, an occurrence that could be confused with an intervention effect
Instrumentation	Measurement of outcomes changes over time in a way that could be confused with an intervention effect
Selection maturation interaction	Time-dependent changes vary systematically in different types of experimental units

8.3.3 Construct validity

Construct validity refers to the validity of inferences about the higher order constructs that represent sampling variables. Construct validity requires an adequate elucidation (or explication) of the constructs and an adequate assessment of the variables sampled. Within implementation research, the constructs include features of interventions, settings or outcomes. For example, the term 'audit' describes any process of feeding back performance data within a specified period of time (155). Several attributes of this intervention may vary, such as the content, source, recipient, timing or format of the feedback data. Sufficient knowledge of and agreement upon the main attributes of an audit and feedback intervention demonstrated to be effective are necessary to ensure its replication.

The constructs of the variables sampled within implementation research also require sufficient elucidation. For example, the self-reported practice of consultant gynaecologists is insufficient

as a measure of gynaecology unit performance partly because the practice of individual consultants may not reflect that of all other staff who contribute to the performance of a gynaecology unit. Table 8.4 summarises the main threats to construct validity.

Table 8.4. Threats to construct validity (based on reference (285)).

Threat	**Description**
Inadequate definition of constructs	Failure to adequately define a construct may lead to incorrect inferences about the relationship between operation and construct
Construct confounding	Operations usually involve more than one construct, and failure to describe all the constructs may result in incomplete construct inferences
Mono-operation bias	Any one operationalisation of a construct both under-represents the construct of interest and measures irrelevant constructs, complicating inference
Mono-method bias	When all operationalisations use the same method (e.g. self-report), that method is part of the construct actually studied
Confounding constructs with levels of constructs	Inferences about the constructs that best represent study operations may fail to describe the limited levels of the construct that were actually studied
Intervention sensitive factorial structure	The structure of a measure may change as a result of an intervention, change that may be hidden if the same scoring is always used
Reactive self-report changes	Self-reports can be affected by participant motivation to receive an intervention, motivation that can change after assignment is made
Reactivity to the experimental situation	Participant responses reflect not just interventions and measures but also participants' perceptions of the experimental situation, and those perceptions are part of the intervention construct actually tested
Experimenter expectancies	The experimenter can influence participant responses by conveying expectations about desirable responses, and those expectations are part of the intervention construct as actually tested
Novelty and disruption effects	Participants may respond unusually well to a novel innovation or unusually poorly to one that disrupts their routine, a response that must then be included as part of the intervention construct description
Compensatory equalisation	When the intervention provides desirable goods or services, administrators, staff, or constituents may provide compensatory goods or services to those not receiving the intervention, and this action must then be included as part of the intervention construct description
Compensatory rivalry	Participants not receiving the intervention may be motivated to show they can do as well as those receiving the intervention, and this compensatory rivalry must then be included as part of the intervention construct description
Resentful demoralisation	Participants not receiving a desirable intervention may be so resentful or demoralised that they may respond more negatively than otherwise, and this resentful demoralisation must then be included as part of the intervention construct description
Intervention diffusion (contamination)	Participants may receive services from an intervention to which they were not assigned, making construct descriptions of both groups more difficult

8.3.4 External validity

External validity refers to the extent to which a causal relationship holds over variations in persons, settings, treatments, and outcomes. This involves inferring whether a causal relationship established within an experiment can be generalised beyond that experiment. Table 8.5 lists the main threats to external validity.

Targets of generalisation can be diverse:

- Narrow to broad, e.g. whether results of implementation studies including gynaecologists can be generalised to all secondary care clinicians
- Broad to narrow, e.g. whether results of studies involving a wide range of secondary care clinicians can be generalised to gynaecologists
- At a similar level, e.g. whether results of studies including Scottish gynaecologists can be generalised to gynaecologists in the North of England
- To a different kind, e.g. whether results of studies involving general surgeons can be generalised to gynaecologists
- Random sample to population members, e.g. to what degree results from a random sample of gynaecologists can be generalised to the whole population of gynaecologists

Generalising from single studies is problematic. The design of experimental studies often requires specification of the range or heterogeneity of persons, treatments, or outcomes considered. If one or more of these variables is too heterogeneous, real associations may be missed within a combined analysis. However, narrower specifications can substantially limit generalisability. Systematic reviews are useful because they can provide information about whether a causal effect holds over a wider (more heterogeneous) range of contexts.

Table 8.5. Threats to external validity (based on reference (285)).

Threat	Description
Interaction of the causal relationship with units	An effect found with certain kinds of units might not hold if other kinds of units had been studied
Interaction of the causal relationship over intervention variations	An effect found with one intervention variation might not hold with other variations of that intervention, or when that intervention is combined with other treatments, or when only part of that intervention is used
Interaction of the causal relationship with outcomes	An effect found on one kind of outcome observation may not hold if other outcome observations were used
Interactions of the causal relationship with settings	An effect found in one kind of setting may not hold if other kinds of settings were to be used
Context-dependent mediation	An explanatory mediator of a causal relationship in one context may not mediate in another context

8.4 Appropriateness of study designs

Factors other than validity influence the choice of study design. These factors primarily include resources available and relevance to the needs of research programmes. Experimental and some quasi-experimental studies are relatively expensive and time-consuming to plan and conduct. Less rigorous opportunistic studies can still usefully contribute to the knowledge base built up within a programme of research if their associated limitations are acknowledged. The designs and methods of the studies described in this thesis therefore need to be appraised in the context of SPCERH's work plan:

- Development of clinical guidelines and monitoring standards through clinical audit
- Education, training and facilitation of professionals providing reproductive healthcare
- Provision of coordination and advice
- Developing ways of implementing effective practice through research

The strengths and weaknesses of individual studies within this thesis have been discussed in previous chapters, applying criteria for methodological quality in two (Chapters 5 and 7)(134;231). The main objective of this chapter is to apply a more generic framework to appraise the strengths and weaknesses of the studies with respect to their validity, cost and relevance to the needs of the SPCERH programme. The framework best fits the appraisal of intervention studies; hence the defined threats to validity do not always appear relevant to the descriptive and observational studies described below. However, the framework has been applied pragmatically to highlight key lessons learned from each study and the overall critique is intended to be illustrative rather than comprehensive.

8.5 Appraisal of studies

8.5.1 Attributes of clinical recommendations that influence change in practice following audit and feedback

This observational study measured pre- and post-intervention compliance in gynaecology units, assessed by a case note review, following an intervention consisting of an audit and feedback programme (Table 8.6). Multi-level modelling was used to examine the relationship between thirteen attributes of clinical practice recommendations and compliance with the recommendations before and after the intervention.

Table 8.6. Appraisal of the validity of the observational study.

Study objective: To determine which attributes of recommendations from a national audit project best explain the extent of their adoption into clinical practice (Chapter 2)

Relevant threats to validity	**Strengths**	**Limitations**
Statistical conclusion validity		
Violation of assumptions of statistical tests	Multi-level modelling adjusted for clustering	
Internal validity		
Ambiguous temporal precedence	Compliance measured before and after intervention	
Regression	Regression effects controlled for in model	
Construct validity		
Construct confounding	Elucidation of intervention, measures of clinical practice, and rating of recommendation attributes Association between attributes and change in practice controlled for in model	Confounding related to observational study design Changes in practice also possibly related to residual confounders
External validity		
Interaction of association with study units	Generalisable to gynaecology units in Scotland	Generalisable to other study settings uncertain
Interaction of association with intervention variations		Association may not hold for variations of audit and feedback methods or other types of intervention
Interaction of association with study context	External evidence of convergent findings in primary care	

Statistical conclusion validity. The use of multi-level modelling, incorporating individual hospital effects, was justified given the marked variation in practice observed among different hospitals. Analyses based on patient level data, which do not account for 'clustering' effects, might have over-emphasised the significance of any results (152).

Internal validity. As changes in clinical practice were measured before and after the intervention, ambiguous temporal precedence is not a threat. Recommendations less *compatible with clinician norms and values* were associated with greater improvements in clinical practice, possibly because of greater potential for change due to low pre-intervention compliance. The multi-level model included an interaction term that accounted for temporal changes (130). Therefore, the association between lower compatibility and changes in practice cannot solely be attributed to improvements upon more extreme low levels of pre-intervention compliance (regression effects).

Construct validity. The constructs comprised the following:

- Participants: gynaecology units
- Intervention: attributes of recommendations
- Outcomes: compliance and changes in compliance
- Setting: national audit and feedback project in secondary care in Scotland

The attributes of the guideline recommendations are categorised as the intervention in this instance – although conventionally they represent effect modifiers and the audit and feedback project represents the intervention.

The attributes were rated by end-point users, i.e. a consensus panel of gynaecologists. Different results might have been obtained had the attributes been rated in another way, such as by a panel of researchers or using a different style of consensus development.

Construct confounding related to study design can hinder the interpretation of outcomes. There were no control groups of gynaecology units. The effect estimates of audit and feedback may have been biased (inflated) by a combination of self-selection by participating units (16 out of 26 units in Scotland participated), and history and maturation effects. If the association between recommendation attributes and changes in compliance were to be assessed in a different experimental context, such as a randomised trial of audit and feedback, the effect estimates might be reduced. Hence, the association between attributes and changes in compliance might be weaker if tested within studies of greater internal validity.

Construct confounding may also present difficulties in interpretation of the associations between changes in practice and the recommendation attributes. In crude terms, for each attribute changes in practice were compared between one group of recommendations possessing that attribute and another group without. Changes were attributed to effects of the attributes, controlled for the potential confounders of other attribute effects and pre-intervention compliance. Residual confounding effects may have confused the real strength and/or direction of the associations. *Compatibility with clinician norms and values* was significantly correlated with the seven other attributes and might represent a general marker for a range of attributes that influence practice, including unknown attributes that remained unadjusted for in the final model.

External validity. The study findings are directly generalisable to gynaecologists participating in national audit projects in Scotland. The observed association may be modified or may not hold over other contexts. For example, different attributes may have influenced change in clinical behaviour following an intervention other than audit and feedback (e.g. interactive educational programmes). But with regard to setting, two attributes, *compatibility* and *requires changed*

routines, had significant and independent effects on compliance in both this and a similar study of audit and feedback in primary care (29). This finding strengthens the likelihood that these two attributes have more generalisable associations with compliance (but not necessarily changes in compliance).

Appropriateness of study. This was an opportunistic study conducted at relatively low cost. It addressed SPCERH's role in developing interventions to support guideline implementation.

8.5.2 Survey of Scottish obstetricians and midwives to assess knowledge of key clinical recommendations from the Report on Confidential Enquiries into Maternal Deaths in the UK 1994-6

It is worth noting that this survey was primarily intended as a descriptive study. In order to illustrate the limitations of using such designs in intervention studies, it will be appraised as an uncontrolled after (post-intervention) study (Table 8.7). Observations, consisting of knowledge and self-reported behaviour, were only made following the intervention, dissemination of the Report (132).

Table 8.7. Appraisal of the validity of the uncontrolled after study.

Study objective: To survey Scottish obstetricians and midwives to assess knowledge of key clinical recommendations from the Report on Confidential Enquiries into Maternal Deaths in the UK 1994-6 (Chapter 3).

Relevant threats to validity	**Strengths**	**Limitations**
Statistical conclusion validity		
Fishing and the error rate problem		Risk associated with lack of a priori hypothesis
Internal validity		
Ambiguous temporal precedence		Cross sectional design
History		Lack of control group
Maturation		Lack of control group
Construct validity		
Inadequate definition of constructs		Response to interviews may under-represent extent of knowledge prompted in vivo by clinical events
Mono-method bias		Only one type of outcome measured
Reactivity to the experimental situation	Efforts made to conceal nature of survey before interviews and to ensure anonymity	Interviewees may have given socially desirable responses
Experimenter expectancies	Standardisation of interviewer schedule	Interviewers may have deliberately or accidently prompted 'appropriate' responses
External validity		
Interaction of the causal relationship with units	High response rate and quasi-random sampling of staff	Findings may not be generalisable or relevant to other professional groups
Interaction of the causal relationship over intervention variations		Findings may not be transferable to other types of confidential enquiries
Context-dependent mediation		Potential effect modification of SPCERH

Statistical conclusion validity. Minimal inferential statistical analysis was performed given the descriptive nature of the study. The only reported statistical test compared median recall of key recommendations among groups exposed in varying degrees to the Report. There was risk of type I error as this hypothesis was tested *post-hoc*.

Internal validity. As no observations were made before the intervention, it was not possible to determine whether the intervention resulted in any change. Respondents who reported having read at least some of the Report or had attended a relevant educational meeting recalled more recommendations compared with those who had not. Yet the timing of the relationship between knowledge and exposure to the Report is unclear (ambiguous temporal precedence). For

example, staff who received or read the Report may already have been more interested in the issues it raised and hence recalled more recommendations.

The absence of a control group meant that no allowance was made for secular trends, including history and maturation. To illustrate the latter, obstetric units conducting their own enquiries may have reached similar conclusions to the Report and might have independently disseminated recommendations to local staff.

Construct validity. The main constructs evaluated initially appear to be clear:

- Participants: junior and senior obstetric medical and midwifery staff
- Intervention: postal dissemination of educational materials
- Outcomes: professional knowledge; self-reported behaviour
- Setting: secondary care in Scotland

On closer scrutiny, the intervention and outcomes merit further elucidation. The dissemination of the Report was supported by SPCERH, via national meetings and its newsletter. Therefore, SPCERH may have represented a co-intervention. One outcome, awareness of key recommendations, may be context-specific. For example, a midwife may not be able to recall recommendations concerning pre-eclampsia when questioned 'out of the blue'. Confronted with a patient at high risk of pre-eclampsia, she might be prompted to recognise the need for senior medical input and warn the patient to be vigilant about possible warning signs. Therefore, the survey method may have under-estimated the true prevalence of professional awareness.

Only one type of outcome, based on self-report, was assessed (mono-method bias). It is not clear whether dissemination of the Report had any other consequences for other outcomes, such as women's perception of care or resource use.

Reactivity to the experimental situation was recognised as a risk. The precise nature of the survey was not stated in advance to prevent staff from making special efforts to consult the Report before the interviews. Nevertheless, in responding to questions about clinical behaviour, staff may have felt pressurised to report what they perceived to represent best practice. In mitigation, the confidential nature of the survey and its aim to assess dissemination of the Report rather than individual competence were explained to all participants.

Similarly, the interviewers possibly had expectations of what respondents, or subgroups of respondents (e.g. more senior staff), knew about the Report recommendations (experimenter

expectancies). Although efforts were made to standardise the interview schedule and enhance its objectivity, it is feasible that interviewer expectancies led to an over-estimation (or under-estimation) of respondents' knowledge and compliance with the recommendations.

External validity. It is possible that staff who recalled more recommendations were more likely to respond than those who declined to be interviewed. However, significant response bias was unlikely given the response rate of 97% and quasi-random method of selecting participants. Hence, the findings of this study are generalisable to obstetricians and senior midwives throughout Scotland, and possibly elsewhere in the UK

This may not be the case when generalising more broadly. At face value, obstetricians and midwives are likely to share many characteristics with other health professionals. However, given the established history of conducting confidential enquiries in relation to obstetric events, obstetricians and midwives might be more familiar with and receptive to Confidential Enquiry reports than colleagues in other specialities. Similarly, these findings may not be generalisable to other types of confidential enquiry.

Whether or not SPCERH can be categorised as a co-intervention, the context in which the Report was published represented a potentially important mediator. Scotland contains a relatively close-knit community of obstetricians and gynaecologists, formalised by the development of SPCERH and other national professional bodies. Its prevailing professional culture could act as an effect modifier – although there is no empirical evidence of such an effect.

Appropriateness of study. This study was not designed to assess the effectiveness of national or local dissemination activities. Despite the aforementioned pitfalls in ascertaining professional awareness, the survey indicated which recommendations required reinforcement in future dissemination activities. The survey represented a low cost, opportunistic project, consistent with SPCERH's core audit and dissemination functions.

8.5.3 Survey of Scottish obstetricians to evaluate the impact of four national clinical guidelines on self-reported practice

The survey of obstetricians to assess the impact of four national guidelines represented an uncontrolled before-and-after study (Table 8.8). Observations comprised self-reported behaviour, including responses to vignettes, made in one group of Scottish obstetricians before and after dissemination of the guidelines.

Table 8.8. Appraisal of the validity of the uncontrolled before-and-after study.

Study objective: To survey Scottish obstetricians to evaluate the impact of four national clinical guidelines on self-reported practice (Chapter 4)

Relevant threats to validity	**Strengths**	**Limitations**
Statistical conclusion validity		
Fishing and the error rate problem		Multiple hypothesis testing
Internal validity		
Ambiguous temporal precedence	Pre- and post-intervention observations taken	
Selection	Pre-intervention observations control for post-intervention	
History		External local or national events not controlled for
Maturation		Independently occurring changes in obstetric units not controlled for
Regression		Post-intervention observations selected to include recommendations with greatest scope for improved compliance
Testing		Potential sensitisation of participants to appropriate responses
Construct validity		
Inadequate definition of constructs	Constructs adequately defined	
Mono-method bias		Use of self-reports only
Reactivity to the experimental situation		Participants may have given socially desirable responses
External validity		
Interaction of the causal relationship with units		Low response rates limits generalisability to all obstetricians
Interaction of the causal relationship over intervention variations		Evidence that effect size varied among four guidelines
Interaction of the causal relationship with outcomes		Use of self-reports potentially over-estimated compliance and change in practice
Context-dependent mediation		Potential effect modification of SPCERH

Statistical conclusion validity. There was a risk of type I error because of multiple hypothesis testing. At a significance level of 5%, at least one 'significant' change in practice would have been anticipated in this study. Nevertheless, the overall trend was consistent with improved knowledge and practice; the limited number of obstetricians available for the survey possibly constrained the ability to detect further significant changes.

Internal validity. The sequence of events is clearer with this design, with pre-intervention observations acting as a control for the post-intervention observations. Many characteristics of the study sample were similar when both measurements were taken, as only responses to those replying to both surveys were analysed.

The main disadvantage was the lack of a non-intervention control group, which may have led to an over-estimation of effect. Firstly, maturation effects can occur when the passage of time brings about changes in the study participants independent of the intervention. The obstetricians may have become more familiar with certain clinical practices over time independently of knowledge of the guideline recommendations. Secondly, history bias may have occurred if other local or national events contributed to any apparent improvement in awareness of recommendations, e.g. publication of CEMD reports.

The other threats to internal validity comprised regression and testing effects. For the follow-up survey, those guideline recommendations with greatest scope for improvement in practice were selected. Regression to the mean could have occurred if study recommendations selected on the basis of their more extreme scores (low compliance with guideline recommendations) tended to give subsequent scores closer to the average. Testing effects represented a threat because changes in self-reported practice were assessed over time. Clinicians responding to the follow-up questionnaire may have become sensitised to the most appropriate responses.

Construct validity. The constructs comprised the following:

- Participants: consultants and senior / specialist registrars in obstetrics
- Intervention: the launch of clinical guidelines at a national educational meeting supported by feedback on self-reported performance and postal distribution of the guidelines, occurring under the auspices of a national clinical effectiveness programme.
- Outcomes: self-reported practice, partly in relation to clinical vignettes
- Setting: secondary care in Scotland

Unlike the CEMD survey, participants completed vignettes designed – to a limited degree – to represent realistic clinical scenarios. Hence, responses were (slightly) more likely to represent actual practice. However, only self-reports were assessed (mono-method bias). Participants could plausibly have reacted to the experimental situation by tailoring responses so as to be seen to be complying with the guideline recommendations, hence inflating compliance. Despite the confidential nature of the survey, some obstetricians may have felt under pressure to consult the guidelines and find the 'correct' responses.

External validity. The respondents were a self-selected group; 35% of the sample did not respond and obstetricians unaware of, or not following, the guidelines may have been less likely to respond to the survey. Therefore, the low response to both surveys limits the generalisability of the findings to all obstetricians in Scotland.

In addition, there was limited evidence that the postulated causal relationship varied with the nature of the intervention, i.e. the content of the guideline. There were significant improvements in reported management relating to two guidelines, *The Preparation of the Fetus for Preterm Delivery* and *The Management of Pregnancy in Women with Epilepsy.* However, reported practice in relation to *The Management of Mild, Non-proteinuric Hypertension in Pregnancy* improved little. This was perhaps because the guideline recommendations for this topic were relatively complicated to understand and apply, and established patterns of practice more resistant to change.

Only self-reports were assessed and these may over-estimate actual clinical performance (37). It is possible that both the levels of compliance and changes in compliance observed in this study would not be replicated in a study using outcomes based on actual patient data (129).

The guidelines were disseminated under the auspices of SPCERH and within the obstetric community in Scotland. These factors may have acted as effect modifiers and thus may alter the generalisability of the findings to other contexts.

Appropriateness of study. The primary objective was to audit reported practice following dissemination of the guideline, demonstrating integration of guideline development, dissemination and audit at a national level. This objective was inherited as part of SPCERH's work programme. The time and expense of conducting this survey were low.

8.5.4 Simple interrupted time series analysis to evaluate the impact of a national clinical guideline on the management of women with mild, non-proteinuric hypertension

This evaluation comprised an interrupted time series analysis (Table 8.9). Multiple observations, compliance with guideline recommendations assessed by a case note review, were taken before and after an intervention: dissemination and implementation of the guideline. The objective was to detect whether the intervention had an effect greater than any underlying trends in practice (134).

Table 8.9. Appraisal of the validity of the interrupted time series analysis

Study objective: To conduct an interrupted time series analysis to evaluate the impact of a national clinical guideline on the management of women with mild, non-proteinuric hypertension (Chapter 5)		
Threats to validity	**Strengths**	**Limitations**
Statistical conclusion validity		
Low statistical power		Numbers of cases sampled per time point and observations decided on pragmatic grounds
Violated assumptions of statistical tests	Logistic regression modelling adjusted for clustering per time point	
Fishing and the error rate problem	Main outcomes determined prior to analysis	
Unreliability of measures	Use of objective outcomes and training of data collectors	Degree of inter-observer variation unknown
Restriction of range	Outcomes modified (pre-analysis) to enhance scope for detecting change	
Heterogeneity of units		Variable responses to intervention among maternity units may obscure causal effects
Internal validity		
Selection bias	Same units assessed pre- and post-intervention; no temporal change in case mix	
History	External events judged unlikely to have exerted any significant effects	
Maturation	Pre-intervention trends act as control for post-intervention	
Regression	Analysis of trends allows estimation of effects related to regression	
Attrition	Post-intervention data available for all four units; 85% of case notes analysed for appropriateness of management	
Instrumentation	Standardised data collection tools	Data collectors not blinded
Construct validity		
Inadequate definition of constructs	Constructs defined, including limitations of patient follow-up data	
Mono-operation bias	Study evaluated one method of audit and feedback	
Mono-method bias	Study outcomes consistent with survey of obstetrician practice	Outcomes from case note review, not (e.g.) patient views
Intervention sensitive factorial structure	Unlikely given absence of significant effects on practice	
Reactivity to the experimental situation	Not possible given retrospective nature of study	
Novelty and disruption effects	Unlikely given precedence of similar interventions and low intensity of intervention	
External validity		
Interaction of the causal relationship with units	Findings relevant to other obstetric and midwifery staff	Limited generalisability to other professional groups
Interaction over intervention variations		Potential effect modification of guideline recommendations
Context-dependent mediation		Potential effect modification of SPCERH

Statistical conclusion validity. The main outcomes for this study were determined in advance of the analysis. However, the criteria for appropriate care were relaxed following the initial estimations of compliance to deal with the threat of restricted range of the outcome measure. This augmented the sensitivity of the outcome measures and the ability of the study to detect changes in practice. The study was analysed appropriately using time series techniques, employing logistic regression modelling adjusted for the clustering per time point.

Four factors probably impaired the ability of the analysis to detect significant changes in practice. Firstly, and despite attempts to standardise data collection, the level of inter-observer variation was unknown. Given the relative complexity of data extraction, it is likely that random error reduced the precision of the effect estimates.

Secondly, it was envisaged that 40 cases would provide sufficiently reliable estimates for each time point. A mean of 35 cases per month were available for the measurement of initial diagnosis whilst a mean of 30 cases per month were available to measure the appropriateness of subsequent clinical management. Given the wide error around each data point in the time series, any small to moderate changes in practice may not have been detected. Visual examination of the graph for appropriate diagnosis suggests a small increase in the intercept, raising the possibility of a type II error. There was little indication of any change in the intercept or gradient for subsequent clinical management, suggesting that a larger study sample would have been insufficient to detect a significant change.

Thirdly, the use of more post-intervention time points would have reduced ambiguity of the diagnosis process trends. Following a non-significant post-intervention increase in the appropriateness of diagnosis, there was evidence of a 1.2% decay in compliance per month. Paradoxically, this decay could have caused an apparent intervention effect. Decreasing compliance in the last five to six data points contributed to the negative slope of the fitted line, hence increasing the level of effect at the intercept (start of the post-intervention period). Hypothetically, had compliance subsequently risen again the negative slope of the fitted line would have been reduced, thus diminishing the intervention effect. Without further data points (beyond 12 months post-intervention) it was not possible to determine whether the increased post-intervention compliance for the appropriateness of diagnosis was artefactual or real.

Fourthly, the four study units were heterogeneous, representing a range of self-reported practice, locations and hospital types. These different units responded variably to the intervention. Unadjusted for trends, the mean pre- to post-intervention change in the appropriateness of diagnosis was 5.3% with a range of –0.4% to 12.0% among the four units. Similarly, the mean

pre- to post-intervention change in the appropriateness of management was 3.7% with a range of –2.3% to 10.2%. Although important for external validity, high levels of heterogeneity tend to obscure causal relationships.

Internal validity. Simple (uncontrolled) interrupted time series analyses allow for secular changes resulting from maturation or regression to the mean to be estimated. The main threats to internal validity comprised selection, history, attrition and instrumentation effects.

Selection bias can be ruled out as the same units were assessed before and after the intervention. Furthermore, there was no evidence of any change in case mix that could have altered the outcomes following the intervention period.

History, other events occurring between the start of the intervention and post-intervention observations, could have improved compliance in the absence of the intervention. Potentially confounding local and national events were investigated and judged unlikely to have exerted any significant effect on practice within the study units. As this identification was retrospective, and in the absence of a control group, it remains possible that events exerting significant confounding effects might not have been detected.

Attrition would have represented a threat had no data been available for one or more of the maternity units post-intervention. However, although all 1263 case notes were assessed for compliance with the diagnostic criteria, sufficient data was available on only 1081 (85%) for the assessment of subsequent management. There was no indication of any trend in the proportion of cases available for the assessment of management, suggesting that attrition over time did not represent a major threat.

Instrumentation bias represents the final threat to internal validity, whereby the way in which data were collected could have changed over the study period. A standard form was used to collect objective data from case notes but data collectors were not explicitly blinded to the hypothesis. The detection of key clinical events or processes in the case notes might have varied according to the vigilance of data collectors. Hence, data collectors' awareness of the hypothesis that clinical care was expected to improve following dissemination of the guideline could have contributed to bias. Given the complexity of interpreting such data in the assessment of compliance, any such effects were unlikely.

Construct validity. The constructs comprised the following:

- Participants: consultant-led maternity units
- Intervention: the launch of a clinical guideline at a national educational meeting supported by feedback on self-reported performance and postal distribution of the guidelines, occurring under the auspices of a national clinical effectiveness programme.
- Outcomes: compliance with the clinical guideline assessed by a case note review
- Setting: secondary care in Scotland

The main outcomes consisted of compliance with criteria set out in the guideline recommendations. Yet the guideline recommendations were relatively complex. In particular, women could move between different levels of care over time, depending upon clinical findings and the results of investigations. Subsequently, collecting data to capture all relevant events over the complete course of a pregnancy would have been prohibitively time consuming and difficult to analyse. The outcomes and data collection therefore focused on the diagnosis and management of women during the first seven days following the initial detection of raised blood pressure, proteinuria or both. The use of these narrower constructs may have prevented the detection of changes in care occurring over longer follow-up periods for each woman.

For logistical reasons, the intervention comprised one of several methods of feeding back data on performance. It is important that this particular operationalisation of audit and the negative findings of the study are not generalised inappropriately to other ways of conducting audit (mono-operation bias).

The method used to measure performance, the case note review, represents part of the outcome construct. This aspect of the study was susceptible to mono-method bias as other outcomes were not elicited, such as women's views on the quality and acceptability of care. Given the lack of change detected with both the case note review and the obstetrician survey (8.5.3), any such other effects seem unlikely.

Other aspects of the study design were unlikely to represent significant threats to construct validity. The intervention could have affected the structure of the data available, independently of the outcome measure (intervention sensitive factorial structure). The format of case notes may have changed over time, possibly in response to the dissemination and implementation of the guideline, allowing better recording of clinical details. The likelihood of such an effect was low given the observed lack of significant change. The retrospective nature of the study protected against participants' (clinical staff) reactivity to the experimental situation. Novelty and disruption effects were unlikely given precedence of similar interventions (i.e. related national standard setting and audit projects) and the low intensity of the intervention locally.

External validity. The main strengths and weaknesses relating to external validity are similar to those raised under sections 8.5.2 and 8.5.3. It is plausible that the four maternity units that agreed to participate in this study were atypical. However, attempts were made to enhance the representativeness of the units by sampling units from different geographical areas in Scotland, comprising two teaching and two district general hospitals.

It is notable that, according to the obstetrician survey, there were no reported improvements in practice in contrast to two other guidelines released simultaneously. Therefore, had the time series analysis been conducted for one of the other topics instead, it is possible than a beneficial effect could have been detected following what essentially represented the same intervention.

Appropriateness of study. This study represented an opportunistic but more rigorous evaluation of the guideline dissemination and implementation strategy than the uncontrolled before-and-after survey of obstetrician practice. A randomised evaluation was not possible given that the guideline had been disseminated throughout Scotland. The recruitment of external controls (i.e. maternity units in Northern England) was considered outside the territory of the SPCERH programme. Although less costly than a randomised evaluation, the time and expense of this study were greater than anticipated because of data collection problems.

8.5.5 The identification of barriers to change and tailoring of a strategy to improve induced abortion care

This critique focuses on the use of a cross-sectional survey, assessing the relationship between unit compliance (measured by a case note review) with two guideline recommendations and psychological measures in clinical staff from gynaecology units (Table 8.10). However, reference will also be made to the supplementary use of open-ended survey questions and semi-structured interviews with lead gynaecologists. Compliance was measured prior to a trial intervention.

Table 8.10. Appraisal of the validity of the cross-sectional study.

Study objective: To identify barriers to the implementation of a clinical guideline on women requesting induced abortion and tailor a strategy to improve care (Chapter 6)

Relevant threats to validity	**Strengths**	**Limitations**
Statistical conclusion validity		
Violated assumptions of statistical tests	Modelling adjusting for cluster effects	
Restriction of range	Use of continuous rather than categorical measures of compliance	
Internal validity		
Ambiguous temporal precedence		Cross-sectional design
Construct validity		
Inadequate definition of constructs	Unit compliance used as proxy measure for individual behaviour	
Construct confounding	Use of supplementary source (interviews with lead gynaecologists) to identify organisational barriers	Use of individual-level theory to explain unit behaviour
Mono-method bias	Combined use of TPB questions, open-ended questions and interviews	
Reactivity to the experimental situation	Use of psychometric testing	
External validity		
Interaction of the causal relationship with units	Acceptable survey response rate of 72%	No data on barriers available from one gynaecology unit Selection bias of survey responders TPB survey findings only apply to staff directly involved in abortion care
Interaction of the causal relationship over intervention variations	Associations differed between two guideline recommendations assessed in TPB survey	

Statistical conclusion validity. Compliance data were analysed as a continuous rather than categorical variable to enhance the ability to detect significant correlations with psychological measures (226). Regression analysis accounted for hospital clustering effects (152).

Internal validity. Cross-sectional surveys can test the strength and direction of an association but cannot provide direct evidence of causality because of ambiguous temporal precedence. In this case staff attitudes may influence compliance with a guideline - but compliance levels may also influence staff attitudes.

Construct validity. The constructs comprised the following:

- Participants: gynaecology units
- Outcomes: association between (pre-intervention) unit compliance and individual psychological measures
- Setting: secondary care in Scotland

It was not possible to obtain data on the performance of individual professionals. Unit compliance was therefore used as a proxy measure for individual behaviour. Different results might have been found if individual-level performance data had been available.

Construct confounding was a risk associated with the use of the survey. As a social cognitive theory, TPB did not represent the most appropriate approach to identifying wider factors (i.e. the full range of constructs) that influence behaviour, such as the organisation and wider environment (235). The interviews with lead gynaecologists did provide such information. Yet this complementary approach was not based upon a theory-derived framework, thus limiting its transferability.

Mono-method bias was avoided by the use of three approaches to identify barriers. The TPB survey was complemented by the interviews with local lead gynaecologists, which tended to focus on organisational aspects, and more specific information about barriers and facilitators given by the open-ended responses to the staff survey.

Reactivity to the experimental situation represents a problem with surveys, whereby respondents may give what they perceive to be the correct responses. Compared with questions that ask clinicians why they follow guidelines or not, psychometric methods may be more valid and reliable in the identification of individually-mediated barriers and facilitators. The former describe clinicians' reported *reasons* for their actions but these reasons are not necessarily the same as the *causes* of their behaviour. For example, the TPB questionnaire findings indicated that attitudinal factors were associated with unit compliance to offer an assessment appointment. These factors were not identified from open-ended responses possibly because of a reluctance to admit to negative attitudes.

External validity. The generalisability of the associations found to other gynaecology units was limited in three respects. Firstly, no data were available for one gynaecology unit (unit C). Pre-intervention compliance levels with the two guideline recommendations assessed in the TPB

survey were in the lowest quartiles for this unit. The inclusion of this poorer performing unit may have modified the associations found.

Secondly, the effective survey response rate was 72%, which generally suggests a representative sample. However, there was an under-representation of junior medical staff sampled; a more representative sample could have produced different results. For example, perceived behavioural control (PBC) was lowest for the offer of an assessment appointment within five days of referral. Had more junior medical staff responded, it is plausible that PBC would be even lower – as junior medical staff tend to have less operational control within gynaecology units compared with more senior staff. On regression analysis, there was weak evidence that PBC predicted unit pre-intervention compliance ($p=0.095$); a stronger association might have been found had more junior staff responded.

Thirdly, the survey findings are generalisable to clinical staff directly involved in the provision of abortion care. The beliefs and intentions of staff in the wider organisation, which were not ascertained, may differ and thus limit broader generalisation. Combining methods to identify barriers partly circumvented this limitation.

The interaction of the associations also differed with respect to the two guideline recommendations (or intervention variations) assessed by the TPB questionnaire. Individual professionals' control over the offer of contraception supplies at discharge was notably greater than that for the offer of an assessment appointment. This represented an important finding rather than a weakness of the study design.

Appropriateness of study. This work contributed both to the tailoring of the ImpACT intervention and understanding of its (lack of) effect. The combined approach to the identification of barriers to and facilitators of guideline implementation was more resource-intensive than anticipated.

8.5.6 Cluster randomised trial of a strategy, delivered within a national clinical effectiveness programme, to improve implementation of a clinical guideline on women requesting induced abortion

The evaluation of a strategy to support the implementation of the guideline, *The Care of Women Requesting Induced Abortion*, represented a cluster randomised controlled trial (Table 8.11). Groups of participants (gynaecology units), were randomly allocated to intervention and control arms, and differences in the outcomes (compliance with key guideline recommendations), attributed to the intervention.

Table 8.11. Appraisal of the validity of the cluster randomised controlled trial

Study objective: To evaluate the effectiveness of a strategy to improve implementation of a clinical guideline on women requesting induced abortion (Chapter 7)		
Threats to validity	**Strengths**	**Limitations**
Statistical conclusion validity		
Low statistical power		Limited number of clusters, failed matched randomisation, ceiling effects and limited follow up period
Violated assumptions of statistical tests	Adjustment for clustering effects	
Fishing and the error rate	Main outcomes determined prior to analysis	
Unreliability of measures	Objective outcomes used for case note review; Reliability of patient survey questions previously established	
Heterogeneity of units		Potential for variability in responses to intervention
Unreliability of intervention implementation	Pragmatic study testing national rather than local implementation strategy	
Internal validity		
Ambiguous temporal precedence	Prospective design	
Selection, history, maturation & regression	Protection by random allocation of intervention	
Attrition	Completeness of sampling for case note review; Similar characteristics of respondents to patient survey in intervention and control arms	
Construct validity		
Inadequate definition of constructs	Detailed definition of intervention constructs	
Confounding constructs with levels of constructs	Recognised low intensity of interventions to promote structured case notes and patient information	
Mono-method bias	Combined outcome data from case notes and patient survey	
Intervention sensitive factorial structure	Unlikely to be related to promotion of structured case record	
Novelty and disruption effects	Familiarity with audit and feedback, and clinical effectiveness projects	
Compensatory equalisation	Prevented by cluster randomisation	
Compensatory rivalry	Intervention units not explicitly identified	
Resentful demoralisation	Unlikely given lack of intervention effect	
Intervention diffusion (contamination)	Minimised by cluster randomisation	
External validity		
Interaction of the causal relationship with units	Generalisability to gynaecology units	Generalisability to other specialties
Interaction of intervention variations		Findings may vary if strategy or choice of guideline changed
Context-dependent mediation		Potential effect modification of SPCERH

Statistical conclusion validity. There were several strengths relating to statistical conclusion validity. These included the determination of five key outcomes prior to data collection and the use of appropriate statistical techniques to adjust for clustering effects. The outcome measures were reliable: the case note review was based upon objective process data; and the reliability of patient survey questions established by previous work (263).

The power of the study was limited by several factors: the limited number of clusters; the unreliability of pre-intervention estimates of compliance and subsequent failure of matched randomisation; ceiling effects related to several outcomes; and the limited follow up period. As discussed in Chapter 7 (7.5.3.1), an exploration of trends in compliance and information on the process of local implementation suggest that insufficient power is unlikely to explain the lack of an intervention effect.

A range of gynaecology units was recruited and varied (for example) in size and teaching status. The heterogeneity of the units and subsequent potential for variability in responses to the intervention may have obscured causal effects. A crude sub-group analysis for one primary outcome (Chapter 7.5.3.2) did at least suggest that gynaecology units with low pre-intervention compliance were no more likely to respond to the intervention than controls.

The ImpACT intervention was delivered in a standardised manner to all of the intervention gynaecology units. There was evidence that local implementation efforts varied substantially (Chapter 7.4.4). However, the study was of a pragmatic nature and not designed to ensure standardised local implementation.

Internal validity. Randomised trials counter many of the aforementioned threats to internal validity, including selection, history and maturation effects. The principal remaining threat to internal validity was attrition bias, if loss to follow-up of outcome measures in the intervention and control arms had occurred systematically. Attrition bias was unlikely for the case note review, given the similarity in the characteristics of the patients in each arm and the use of complete groups or random samples of women undergoing induced abortion in the study units. Attrition bias represented a more plausible threat to the comparison of compliance in the patient survey; the overall response rate was 49%, and 7% lower in the intervention arm. However, patient characteristics were similar in the two arms.

Construct validity. The constructs comprised the following:

- Participants: Gynaecology units providing abortion care
- Intervention: A tailored package, deliverable by a national clinical effectiveness programme, comprising audit and feedback, outreach educational meetings, dissemination of structured case records, and promotion of a patient information booklet
- Outcomes: Compliance with guideline recommendations measured by a case note review and patient survey
- Setting: Secondary care in Scotland

The intervention constructs were more complex than those in the aforementioned studies. Not only was the intervention multi-faceted; each component of the package can be broken down into a number of constituents. For example, the audit and feedback component comprised the feedback of anonymised, comparative unit performance data six months following data collection from a national clinical effectiveness programme to clinical staff in gynaecology units. Furthermore, the interventions used were specifically set up within a research programme and largely delivered by a researcher. Hence, this one component of the ImpACT strategy represented a complex intervention in itself.

Confounding effects can occur in relation to different levels of constructs. In this case, the promotion of structured case notes and patient information should not be confused with the actual provision of these materials in the interpretation of the findings. As used within the trial, the former represent relatively weaker interventions. Similarly, the intensity of other aspects of the interventions delivered locally could have been greater, potentially leading to different effects.

Mono-method bias was avoided by use of a case note review and patient survey – with reasonable consistency demonstrated for the majority of outcomes assessed by both methods. In addition, the patient survey incorporated measures of patient satisfaction.

Treatment sensitive factorial structure represented a potential effect. The promotion of structured case notes could have led to improved recording of clinical actions and hence improved compliance in the intervention arm. This effect was unlikely because the process evaluation did not suggest greater uptake of structured case notes in the intervention arm.

The implementation of the implementation strategy in the intervention units is likely to have engendered little of a novelty effect; most participants were reasonably familiar with the main constructs of the interventions (e.g. audit) and the content of the guideline. Although national clinical effectiveness programmes represent a relatively new concept in Scotland, many units had already participated in precursor national activities (e.g. GAPS). Awareness of participation in a

research project might have generated greater efforts to improve practice in both intervention and control groups. There was little evidence of this when overall median pre- and post-intervention compliance was compared across several recommendations. The equal if not greater risk might have been related to disruption caused by the interventions engendering negative reactions in a small but significant minority of participants.

Compensatory equalisation constitutes a risk where an intervention provides additional desirable support to intervention units, subsequently resisted by participants because of perceived unfairness to controls. This effect is usually associated with trials randomising individual patients rather than groups of professionals.

Compensatory rivalry represents a threat if those randomly allocated to control groups became competitive, thereby making greater efforts to compensate and improve practice. The likelihood of this was reduced within the trial by not publicly discussing the identity of gynaecology units during feedback meetings – although it is feasible that knowledge of random allocation may have diffused through informal professional networks. In contrast, resentful demoralisation seems unlikely to have occurred among the control groups, given the absence of any differences in the main outcomes or processes to support implementation of the guideline recommendations.

Intervention diffusion (contamination) was minimised by the use of a cluster randomised design. Hence control group participants were unlikely to receive any aspect of the interventions.

External validity. The study findings apply to all Scottish gynaecology units. As described above (8.5.2), the study intervention took place within the broader context of a clinical effectiveness programme, which represents a potential effect modifier. Generalising from a narrow to a broad spectrum, it is possible that causal effects may have been different in other groups of professionals because of its novelty value, especially in those previously little exposed to similar interventions or national collaborations.

The causal relationship could also vary according to modifications of the strategy (i.e. content and intensity) or to changes in context (i.e. outwith SPCERH). A combined analysis of similar intervention packages would be required to explore such variations.

Appropriateness of study. The trial tested an intervention package that could reasonably be expected to be delivered by a national clinical effectiveness programme, such as SPCERH. The trial was relatively costly and time-consuming to conduct. However, it addressed the core

SPCERH objectives of supporting and evaluating guideline dissemination and implementation activities.

8.6 Discussion

8.6.1 The utility of the framework

The framework enabled a systematic appraisal of individual studies, highlighting their relative strengths and weaknesses. Earlier discussions of individual studies (in Chapters 2 to 7) tended to focus on statistical conclusion validity and internal validity. The framework was useful in prompting other considerations related to construct and external validity, issues integral to the transferability of research findings.

There were two limitations to this exercise. Firstly, the framework was not necessarily applied comprehensively in the appraisal of all studies. The intention was to focus on issues most relevant to individual types of study, such as the greater internal validity associated with randomised evaluations. Secondly, the categorisation of certain threats is disputable. For example, in the uncontrolled before-and-after survey of obstetrician practice (8.5.3), the use of self-reports can be seen as a threat to internal validity. It was categorised as a threat to external validity because the changes in compliance observed might not have been reproduced had actual patient data been used. According to the framework by Shadish *et al*, this represented a potential interaction of the 'causal relationship' with the study outcomes (285).

The application of the framework in this chapter provides an opportunity to comment on the validity and appropriateness of the overall programme of work contributing to the thesis.

8.6.2 Main strengths and weaknesses of the work programme

Statistical conclusion validity. Three issues arose consistently throughout the work programme: multiple hypothesis testing, statistical power; and appropriateness of analyses.

In earlier studies, the uncontrolled after and the uncontrolled before-and-after surveys, hypotheses were not specified in advance and their interpretation was thus prone to type I error. However, the former was primarily intended as a descriptive study and the later as an audit. In both the interrupted time series analysis and cluster randomised trial, the hypotheses and outcomes were specified in advance.

The main threat to the time series analysis and cluster randomised trial was low statistical power, increasing the potential for type II error. In the time series analysis, power was mainly compromised by the limited numbers of cases per time point and limited number of post-intervention time points. In the randomised trial, power was limited by the number of gynaecology units available, the failure of matched randomisation (largely because of imprecise pre-intervention estimates of compliance) and high pre-intervention compliance for several outcomes. Resources therefore largely limited the power of both studies. However, examination of non-significant trends suggested that type II error was unlikely to explain the lack of demonstrated effect in these studies.

The analyses of four studies appropriately adjusted for clustering effects, thereby reducing the likelihood of type I errors, a problem with studies previously reported in this field (139).

Internal validity. In general, threats to internal validity were addressed to a greater degree by the more rigorous intervention studies (the time series analysis and cluster randomised trial) compared with the weaker evaluations of interventions (the uncontrolled after and the uncontrolled before-and-after studies). The addition of controls enhanced internal validity, countering the effects of history, maturation, regression and selection. The time series analysis and its interpretation accounted for preceding trends in the same group of maternity units whilst randomly allocated gynaecology units acted as controls in the cluster randomised trial. The main limitation of the time series analysis was that its interpretation required making explicit but potentially more fallible judgements about the extent of several threats to validity. In this context, history and instrumentation were considered possible but not probable effects. This judgement was made easier by the absence of any observed significant intervention effect – although it is acknowledged that biases could have operated in other directions, i.e. against an intervention effect.

Other threats meriting specific comment include ambiguous temporal precedence and regression to the mean. Whilst ambiguous temporal precedence limited interpretation of the uncontrolled after and the cross-sectional studies, four studies included pre- and post-intervention observations. Regression to the mean remained a significant problem in the interpretation of the uncontrolled before-and-after study. As mentioned above, regression effects were controlled for the time series analysis and cluster randomised trial, whilst multi-level modelling was used in the observational study (of recommendation attributes).

Construct validity. The explication of study constructs and recognition of confounding emerged as key issues in the structured appraisal of construct validity. What initially appeared to be

straightforward constructs often require further qualification on closer examination. For example, the outcomes from the uncontrolled after survey of professional awareness of CEMD recommendations were specific in that professionals answered questions without the usual prompts of the clinical context.

In general, the study constructs became more complex with increasing sophistication of both designs and interventions. Hence, each component (e.g. audit and feedback) of the ImpACT strategy tested in the cluster randomised trial constituted a relatively complex intervention. In isolation from a much wider body of research, there is a risk of interpreting the cluster randomised trial findings as audit and feedback delivered within a multi-faceted strategy is ineffective in changing professional practice. When the wider body of research is taken into account, it emerges that audit and feedback is variably effective (197).

This, firstly, highlights the importance of systematic reviews in the synthesis of research findings. Secondly, closer scrutiny of the constructs illustrates why two or more studies that appear similar at a superficial level may produce contrasting results. There is a need for a standard taxonomy to describe studies of complex interventions, including their content and level, to help identify features consistently associated with greater effects (286).

External validity. The most distinctive feature of this work was its high generalisability to secondary care professionals targeted by SPCERH activities. All of the studies (except the uncontrolled before-and-after survey) involved assessments of patient care by teams of obstetricians and gynaecologists, and midwifery and nursing staff or surveys of these professionals. The findings of several studies may be generalisable to similar groups of professionals elsewhere in the UK NHS. However, it is not known to what extent the context of a national clinical effectiveness programme (SPCERH) or relevant precursor projects (e.g. GAPS) influenced the outcomes, if at all.

Ironically, in the case of induced abortion care, the close knit nature of the Scottish gynaecological community and presence of academic centres leading work on developing methods of induced abortion may have contributed to the lack of effect demonstrated in the ImpACT trial. Compared with England and Wales, services in Scotland generally appear to be organised more coherently and follow recommendations from the RCOG guideline more frequently (287). Therefore, there may have been greater scope for change and responsiveness to the type of interventions used within ImpACT.

It is also difficult to judge the generalisability of findings from the studies to other groups of professionals in secondary or even primary care. The use of TPB did demonstrate variations in practice associated with professional attitudes and beliefs. Wider testing of this theory among other health care professionals may demonstrate that that certain attitudes and beliefs consistently influence clinical behaviour.

However, the absence of any observed effects in the two main intervention studies, the time series analysis and cluster randomised trial, does not necessarily mean that that none would be observed elsewhere if the interventions or outcomes were varied. It is also possible that a modification of the interventions (e.g. more intensive promotion of structured case notes within ImpACT) would have produced different effects within the same setting. Such modifications would probably need to be substantial to overcome some of the barriers identified, e.g. the complexity of the hypertension guideline or the organisational obstacles faced in improving abortion care.

Other findings from this work programme did suggest that modifying the content of clinical guidelines could influence their subsequent uptake. Results from the observational study indicated that attributes of recommendations were associated with variations in changes in clinical practice. The uncontrolled before-and-after survey of obstetric guidelines provided less direct evidence of variations in reported changes in practice among the four guidelines disseminated.

Appropriateness. All studies met the needs of SPCERH's work programme, in particular: (1) the development of clinical guidelines and monitoring standards through clinical audit; and (2) the development of ways of implementing effective practice through research. Whilst the less rigorous study designs were of limited validity, they did directly contribute to the stated needs of the SPCERH work programme by highlighting gaps in knowledge about recommendations from the CEMD Reports and auditing the dissemination of the four obstetric guidelines.

The range of study designs allowed different types of research questions to be addressed. Both of the correlational studies contributed to knowledge of factors that modify the effectiveness of interventions, i.e. the attributes of guideline recommendations and staff attitudes and beliefs.

In general, there was a trade-off between on one hand, higher statistical conclusion and internal validity, and on the other, lower cost and complexity. Despite limitations in power, the time series analysis and cluster randomised trial demonstrated the feasibility of conducting rigorous evaluations of implementation strategies within a recognised network of clinicians. One

challenge for the future lies in finding ways to improve the validity and impact of future implementation studies within collaborations such as SPCERH.

8.7 Conclusion

The systematic appraisal of the validity of individual studies contributing to this programme of work highlighted their relative strengths and weaknesses. The framework was particularly useful in the detailed appraisal of construct and external validity, key determinants of the transferability of research findings.

The main threat to statistical conclusion validity comprised low statistical power in the time series analysis and cluster randomised trial, increasing the potential for type II error. In contrast, multiple hypothesis testing in the uncontrolled before-and-after survey increased the likelihood of type I error. The analyses of four studies appropriately adjusted for clustering effects, thereby reducing the likelihood of type I errors.

Adding or improving control groups improved internal validity, countering the effects of history, maturation, regression and selection. Although the cluster randomised trial emerged as with highest internal validity, the interpretation of the time series analysis was only limited by the possibility (but not probability) of history and instrumentation effects.

The explication of study constructs and recognition of confounding represented key issues in determining construct validity. The study constructs became more complex with increasing sophistication of both study designs and interventions. Yet, what initially appeared to be straightforward constructs often required further qualification on closer scrutiny. The failure to describe studies according to a common taxonomy contributes to confusion and uncertainty over the effectiveness of interventions to improve professional practice.

The studies were of high generalisability to secondary care professionals targeted by SPCERH activities. However, the absence of any observed effects in the time series analysis and cluster randomised trial does not necessarily mean that that none would be observed in different settings of if the interventions were to be varied.

The cost of the studies increased with growing complexity of design. All studies met the needs of SPCERH's work programme, particularly the development of clinical guidelines and monitoring standards through clinical audit, and the development of ways of implementing effective practice through research.

Chapter 9

Implications for SPCERH and implementation research

This chapter summarises implications for both SPCERH and implementation research on the basis of the work contained within the thesis.

9.1 Implications for SPCERH

The nature of clinical practice recommendations influences their subsequent ability to promote changes in clinical policy and practice. The evaluation of the Gynaecology Audit Project in Scotland (GAPS) recommendation attributes suggested that audit and feedback appeared to be effective in promoting the implementation of recommendations judged to be less compatible with clinician norms and values (Chapter 2). Feedback permitting comparisons among hospitals during the audit programme may therefore have prompted action on recommendations previously regarded as too disruptive or incompatible to implement. This finding may be specific to the particular context of the GAPS project. Different attributes may have influenced change in clinical behaviour following an intervention other than audit and feedback, e.g. interactive educational programmes.

Less direct evidence about the influence of attributes of recommendations on implementation comes from other work in this thesis. The strength of evidence underpinning recommendations appeared relevant to two findings. Firstly, there were observed improvements in practice, albeit self-reported, for recommendations supported by rigorous evidence from The Preparation of the Fetus for Preterm Delivery guideline (Chapter 4). Secondly, historical data from GAPS demonstrated low compliance with two Grade A recommendations (i.e. supported by rigorous evidence) from the guideline, The Care of Women Requesting Induced Abortion. Both of these recommendations (antibiotic prophylaxis or screening, and the use of misoprostol) were subsequently selected as key outcome measures in ImpACT (Chapter 7). Within a ten year period, compliance with both of these recommendations had reached near-optimal levels, suggesting that networks of clinicians do respond to convincing evidence of effectiveness. The problem that remains is how to ensure more rapid and equitable implementation of such recommendations.

Other aspects of clinical practice recommendations appeared to be associated with poor assimilation, as suggested by three studies. Firstly, several recommendations contained within

the 1994-6 CEMD report that were new or contained public health messages were associated with low levels of recall (Chapter 3). Secondly, the actual process of developing measures of compliance with levels of care recommended by the guideline, The Management of Mild, Non-proteinuric Hypertension in Pregnancy, highlighted the complexity of its key recommendations (Chapter 5). Not surprisingly, lower levels of compliance were observed for the more complex packages of care evaluated. In future, such recommendations may require further pre-testing to assess their acceptability to and understanding by clinical staff. Thirdly, ImpACT indicated low compliance with and major barriers to the implementation of recommendations requiring organisational, and to some extent, cultural change (e.g. waiting times for initial assessment appointment, Chapter 6).

When setting priorities, programmes such as SPCERH should attempt to anticipate both the likely responsiveness of professionals and organisations to clinical practice recommendations and (as covered below) what implementation strategy might be most appropriate for the recommendations.

Combined approaches are useful in identifying local needs and potential barriers to implementation. Work within ImpACT highlighted the importance of elucidating both individual and organisational factors (Chapter 6). However, assessing barriers requires time and resources, especially if involving a wide range of units and staff. Sufficient time needs to be incorporated within project plans to allow reflection upon findings and to plan definitive interventions.

Interventions to promote the use of clinical guidelines should be appropriately targeted according to identified needs and barriers. Work developing the ImpACT strategy suggested that a 'ceiling' had been reached on motivating most staff involved in the delivery of abortion care to follow the recommendations (Chapter 6). Therefore, components of the strategy that aimed to increase compliance by influencing individual motivation were unlikely to work. Interventions targeting wider aspects of the organisation might have been more appropriate and effective. However, there is little empirical evidence to support many organisation-level interventions. Further consideration should also be given to the greater use of interventions (such as prompts and reminders) demonstrated to be of moderate effectiveness by systematic reviews. The structured case record was only promoted within ImpACT in a relatively passive manner and scope exists to strengthen this type of intervention.

There is a trade-off between the efficiency of nationally led activities and their potential effectiveness. According to the time series analysis and ImpACT, two nationally led strategies of different levels of intensity were ineffective (Chapters 6 & 7). Their lack of impact may have

been attributable in part to effect modifiers, such as the nature of the guideline recommendations. Arguably, the average cost per hospital unit was relatively low: £1695 per maternity unit for the mild hypertension guideline; and £2067 per gynaecology unit for the induced abortion guideline. The organisation of clinical effectiveness activities at a national level centralises costs and is possibly less expensive compared with the organisation of similar activities locally. It is speculative whether locally led and owned activities can be more effective in changing practice. Nevertheless, future dissemination and implementation activities require further development to enhance local involvement. Work is currently underway within SPCERH to evaluate the acceptability of different approaches to feeding back audit data.

Future evaluations require an explicit recognition of the trade-off between rigour and cost. The cost of the studies increased with growing complexity of design. A range of study designs can be used to address different types of research questions. Surveys of professionals can identify priorities for dissemination activities, although relatively little can be inferred on the effectiveness of dissemination activities. Cross-sectional and observational studies can contribute to knowledge of factors that modify the effectiveness of interventions, including barriers associated with guideline recommendations, professionals and organisations. However, questions about the effectiveness and efficiency of dissemination and implementation strategies need to be addressed by rigorously designed intervention studies.

9.2 Implications for implementation research

Attributes of clinical practice recommendations appear to influence both compliance and behaviour change and need to be considered when planning implementation activities. It is likely that the effects of different implementation strategies may be modified by the attributes of recommendations (Chapter 2). Consideration of the attributes of practice recommendations may assist in the choice of implementation strategy. Further research is required to determine how attributes of recommendations modify the effectiveness of different interventions in different contexts. These studies should focus on behaviour change rather than compliance and use the most robust estimates of behaviour change, preferably from randomised trials.

Assessing barriers requires time and resources, especially if involving a wide range of units and staff. Further time needs to be integrated within project plans to allow sufficient reflection of findings and planning of the definitive intervention(s). The frameworks used must be described in sufficient detail to enhance their reproducibility in other contexts (Chapter 6).

Behavioural theories can contribute to the development of interventions and provide a greater understanding of the underlying barriers to change. Greater use of theory may help explain why interventions work in some contexts but not others, by providing more generalisable evidence of what factors may influence clinical behaviour (Chapter 6). Experience from developing the ImpACT strategy highlights the need to extend behavioural research from individual professionals towards team and organisational levels. The longer-term aim is develop 'diagnostic' tools that can provide an empirical basis for the selection of interventions, i.e. whether individual, team or organisational levels should be targeted

Sufficient sample sizes are required to produce precise estimates of effect. Despite prior sample size calculations, low statistical power represented an important threat to statistical conclusion validity for both the interrupted time series analysis and cluster randomised trial (Chapters 6 & 7). The precision of the time series analysis would have been increased had more data per time point sampled been collected. Similarly in the cluster randomised trial, collecting data from larger pre-intervention samples might have enabled the use of a more powerful matched pairs analysis.

Recruiting more clusters to randomised trials represents a more efficient means of improving power than sampling more cases per cluster. However, the number of gynaecology units available to participate in ImpACT was limited by the national boundary of the clinical effectiveness programme.

Selecting clinical guidelines associated with more scope for improved performance represents another means of increasing power. Paradoxically, such guidelines or their recommendations may represent those that encounter greatest resistance to change, illustrated by the lack of success in improving compliance with selected recommendations on induced abortion.

Opportunistic quasi-experiments can provide evidence of acceptable validity. Adding or improving control groups to intervention studies improves internal validity, progressively countering the effects of history, maturation, regression and selection. The cluster randomised trial appeared to possess the highest internal validity of all the study designs used (Chapter 8). However, the interpretation of the time series analysis was only limited by the possibility (but not probability) of history and instrumentation effects. At a more practical level, gaining access to archive data and developing satisfactory outcome measures based on the case note review unexpectedly increased costs and time taken to complete the time series analysis (Chapter 5).

Study constructs become more complex with the increasing sophistication of study design and interventions. Implementation research requires the establishment of a common conceptual framework within which to describe settings, individuals, targeted behaviours, and interventions (Chapter 8). Hence, it should be possible to identify what features influence the likely effectiveness of interventions. The studies in this thesis were of moderate to high generalisability to secondary care professionals targeted by SPCERH activities. However, the absence of any observed effects in the time series analysis and cluster randomised trial does not necessarily mean that that none would be observed in different professional groups, by varying the interventions or working outwith a clinical effectiveness programme.

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Appendix 2A

Gynaecology Audit Project in Scotland: Audit criteria, pre- and post-intervention compliance, and consensus panel rating of attributes

Topic: induced abortion

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
1. All women requesting abortion should be offered an appointment with a gynaecologist within 5 days of referral	48 (464/967)	56 (577/1037)	**+8**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**9**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**9**
Compatible: compatible with clinicians' current norms and values in practice			**8**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**7**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**5**
Fits patient expectations: is likely to fit in with patient expectations			**8**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**8**
Requires organisational change: requires changes in the way care is organised or additional resources			**8**
Requires changed routines: requires changes to fixed routines or habits			**8**
High profile: has a high profile in educational programmes or the media			**5**
Complex: is complex and requires many steps to do or organise			**7**
Trialable: can be tried out and discarded easily			**2**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**1**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
2. Abortion should be undertaken within 7 days of the consultation with the gynaecologist	81 (783/967)	80 (830/1037)	**-1**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**8**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**9**
Compatible: compatible with clinicians' current norms and values in practice			**8**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**7**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**6**
Fits patient expectations: is likely to fit in with patient expectations			**9**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**7**
Requires organisational change: requires changes in the way care is organised or additional resources			**7**
Requires changed routines: requires changes to fixed routines or habits			**6**
High profile: has a high profile in educational programmes or the media			**5**
Complex: is complex and requires many steps to do or organise			**2**
Trialable: can be tried out and discarded easily			**3**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**1**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
3. In the absence of specific medical or social contra-indications, women undergoing surgical abortion should be managed as day cases.	72 (696/967)	83 (861/1037)	**+11**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**9**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**9**
Compatible: compatible with clinicians' current norms and values in practice			**9**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**7**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**9**
Fits patient expectations: is likely to fit in with patient expectations			**9**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**8**
Requires organisational change: requires changes in the way care is organised or additional resources			**2**
Requires changed routines: requires changes to fixed routines or habits			**2**
High profile: has a high profile in educational programmes or the media			**5**
Complex: is complex and requires many steps to do or organise			**3**
Trialable: can be tried out and discarded easily			**5**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**2**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
4. Gestation need not routinely be confirmed by ultrasound scan. The method of abortion may often be decided on the basis of clinical estimation of uterine size.	61 (590/967)	59 (612/1037)	**-2**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**8**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**7**
Compatible: compatible with clinicians' current norms and values in practice			**9**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**3**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**3**
Fits patient expectations: is likely to fit in with patient expectations			**6**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**7**
Requires organisational change: requires changes in the way care is organised or additional resources			**2**
Requires changed routines: requires changes to fixed routines or habits			**5**
High profile: has a high profile in educational programmes or the media			**2**
Complex: is complex and requires many steps to do or organise			**2**
Trialable: can be tried out and discarded easily			**7**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**2**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
5. All women requesting induced abortion should begin regular cervical cytology screening, regardless of age.	46 (445/967)	61 (633/1037)	**+15**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**8**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**7**
Compatible: compatible with clinicians' current norms and values in practice			**7**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**1**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**3**
Fits patient expectations: is likely to fit in with patient expectations			**5**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**2**
Requires organisational change: requires changes in the way care is organised or additional resources			**2**
Requires changed routines: requires changes to fixed routines or habits			**4**
High profile: has a high profile in educational programmes or the media			**5**
Complex: is complex and requires many steps to do or organise			**1**
Trialable: can be tried out and discarded easily			**2**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**1**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
6. The woman's rhesus status should be ascertained, and Rh prophylaxis given following abortion, if indicated.	97 (938/967)	97 (1006/1037)	**0**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**9**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**9**
Compatible: compatible with clinicians' current norms and values in practice			**9**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**9**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**9**
Fits patient expectations: is likely to fit in with patient expectations			**8**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**5**
Requires organisational change: requires changes in the way care is organised or additional resources			**1**
Requires changed routines: requires changes to fixed routines or habits			**1**
High profile: has a high profile in educational programmes or the media			**5**
Complex: is complex and requires many steps to do or organise			**1**
Trialable: can be tried out and discarded easily			**6**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**1**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
7. Doctors managing induced abortion should have a policy for identifying and treating those women at risk of gential tract infection	22 (213/967)	31 (321/1037)	**+9**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**9**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**8**
Compatible: compatible with clinicians' current norms and values in practice			**7**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**7**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**9**
Fits patient expectations: is likely to fit in with patient expectations			**3**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**4**
Requires organisational change: requires changes in the way care is organised or additional resources			**7**
Requires changed routines: requires changes to fixed routines or habits			**7**
High profile: has a high profile in educational programmes or the media			**6**
Complex: is complex and requires many steps to do or organise			**7**
Trialable: can be tried out and discarded easily			**6**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**2**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
15. Before she is discharged, the patient should have agreed on a contraceptive plan and should have been given contraceptive supplies.	92 (890/967)	86 (892/1037)	**-6**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**9**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**9**
Compatible: compatible with clinicians' current norms and values in practice			**8**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**9**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**7**
Fits patient expectations: is likely to fit in with patient expectations			**8**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**2**
Requires organisational change: requires changes in the way care is organised or additional resources			**2**
Requires changed routines: requires changes to fixed routines or habits			**2**
High profile: has a high profile in educational programmes or the media			**8**
Complex: is complex and requires many steps to do or organise			**5**
Trialable: can be tried out and discarded easily			**3**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**2**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
18. A follow-up appointment, either at the hospital, or with the referring doctor, should be given to every patient.	54 (522/967)	69 (716/1037)	**+15**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**9**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**6**
Compatible: compatible with clinicians' current norms and values in practice			**5**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**3**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**6**
Fits patient expectations: is likely to fit in with patient expectations			**5**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**2**
Requires organisational change: requires changes in the way care is organised or additional resources			**7**
Requires changed routines: requires changes to fixed routines or habits			**5**
High profile: has a high profile in educational programmes or the media			**3**
Complex: is complex and requires many steps to do or organise			**3**
Trialable: can be tried out and discarded easily			**2**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**2**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
19. The follow-up appointment should be within 14 days of the abortion.	5 (48/967)	32 (332/1037)	**+27**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**8**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**9**
Compatible: compatible with clinicians' current norms and values in practice			**2**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**3**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**5**
Fits patient expectations: is likely to fit in with patient expectations			**3**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**3**
Requires organisational change: requires changes in the way care is organised or additional resources			**6**
Requires changed routines: requires changes to fixed routines or habits			**6**
High profile: has a high profile in educational programmes or the media			**2**
Complex: is complex and requires many steps to do or organise			**2**
Trialable: can be tried out and discarded easily			**2**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**2**

Laparoscopic sterilisation

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
38. In almost all cases, sterilisation should be refused to women under the age of 25 and reversible methods of contraception advised.	94 (928/988)	96 (1065/1115)	**+2**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**9**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**9**
Compatible: compatible with clinicians' current norms and values in practice			**8**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**7**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**8**
Fits patient expectations: is likely to fit in with patient expectations			**6**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**2**
Requires organisational change: requires changes in the way care is organised or additional resources			**2**
Requires changed routines: requires changes to fixed routines or habits			**5**
High profile: has a high profile in educational programmes or the media			**5**
Complex: is complex and requires many steps to do or organise			**2**
Trialable: can be tried out and discarded easily			**3**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**2**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
39. Prior to sterilisation, it should be verified, by gynaecological history taking and examination, that a more radical operation is not indicated.	52 (513/990)	52 (592/1139)	**0**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**5**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**5**
Compatible: compatible with clinicians' current norms and values in practice			**3**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**5**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**6**
Fits patient expectations: is likely to fit in with patient expectations			**6**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**2**
Requires organisational change: requires changes in the way care is organised or additional resources			**2**
Requires changed routines: requires changes to fixed routines or habits			**5**
High profile: has a high profile in educational programmes or the media			**3**
Complex: is complex and requires many steps to do or organise			**4**
Trialable: can be tried out and discarded easily			**2**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**2**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
42. Pre-sterilisation counselling should include enquiry into any disharmony within the current relationship.	45 (445/988)	47 (538/1139)	**+2**

Attribute	*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care	**7**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice	**7**
Compatible: compatible with clinicians' current norms and values in practice	**6**
Key feature: essential to the whole set of recommendations and to the ultimate goals	**6**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses	**5**
Fits patient expectations: is likely to fit in with patient expectations	**6**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly	**2**
Requires organisational change: requires changes in the way care is organised or additional resources	**2**
Requires changed routines: requires changes to fixed routines or habits	**6**
High profile: has a high profile in educational programmes or the media	**3**
Complex: is complex and requires many steps to do or organise	**2**
Trialable: can be tried out and discarded easily	**2**
Requires new knowledge or skills: requires the learning of new knowledge or skills	**2**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
43. The fact that the patient has been counselled regarding failure rate, complications and irreversibility should be documented in the case notes as well as appearing on a printed consent form.	87 (860/988)	90 (1026/1139)	**+3**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**9**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**9**
Compatible: compatible with clinicians' current norms and values in practice			**8**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**9**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**8**
Fits patient expectations: is likely to fit in with patient expectations			**6**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**5**
Requires organisational change: requires changes in the way care is organised or additional resources			**2**
Requires changed routines: requires changes to fixed routines or habits			**2**
High profile: has a high profile in educational programmes or the media			**7**
Complex: is complex and requires many steps to do or organise			**2**
Trialable: can be tried out and discarded easily			**2**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**2**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
44. Prior to sterilisation, women should be given an information leaflet summarising the various factors covered in the counselling.	7 (70/988)	8 (97/1139)	**+1**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**8**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**8**
Compatible: compatible with clinicians' current norms and values in practice			**7**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**6**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**7**
Fits patient expectations: is likely to fit in with patient expectations			**7**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**5**
Requires organisational change: requires changes in the way care is organised or additional resources			**5**
Requires changed routines: requires changes to fixed routines or habits			**2**
High profile: has a high profile in educational programmes or the media			**5**
Complex: is complex and requires many steps to do or organise			**2**
Trialable: can be tried out and discarded easily			**6**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**1**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
45. The likelihood of a less acceptable menstrual pattern following sterilisation should be discussed with current users of the contraceptive pill.	3 (10/339)	7 (34/423)	**+4**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**8**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**8**
Compatible: compatible with clinicians' current norms and values in practice			**6**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**6**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**7**
Fits patient expectations: is likely to fit in with patient expectations			**6**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**3**
Requires organisational change: requires changes in the way care is organised or additional resources			**2**
Requires changed routines: requires changes to fixed routines or habits			**5**
High profile: has a high profile in educational programmes or the media			**5**
Complex: is complex and requires many steps to do or organise			**2**
Trialable: can be tried out and discarded easily			**5**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**2**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
47. Filshie clips represent the tubal occlusion technique of choice.	62 (619/998)	76 (866/1139)	**+14**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**8**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**7**
Compatible: compatible with clinicians' current norms and values in practice			**6**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**5**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**8**
Fits patient expectations: is likely to fit in with patient expectations			**5**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**2**
Requires organisational change: requires changes in the way care is organised or additional resources			**5**
Requires changed routines: requires changes to fixed routines or habits			**5**
High profile: has a high profile in educational programmes or the media			**3**
Complex: is complex and requires many steps to do or organise			**2**
Trialable: can be tried out and discarded easily			**2**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**2**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
48. Except where there are medical or social geographical contra-indications, laparoscopic sterilisation should be performed as a day case.	72 (719/998)	79 (900/1139)	**+7**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**9**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**9**
Compatible: compatible with clinicians' current norms and values in practice			**9**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**7**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**9**
Fits patient expectations: is likely to fit in with patient expectations			**8**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**8**
Requires organisational change: requires changes in the way care is organised or additional resources			**2**
Requires changed routines: requires changes to fixed routines or habits			**2**
High profile: has a high profile in educational programmes or the media			**7**
Complex: is complex and requires many steps to do or organise			**2**
Trialable: can be tried out and discarded easily			**2**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**2**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
49. A post-MRCOG gynaecologist should perform, or be present at, all laparoscopic sterilisations and should confirm occlusion of both fallopian tubes.	88 (878/988)	80 (913/1139)	**-8**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**8**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**9**
Compatible: compatible with clinicians' current norms and values in practice			**7**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**7**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**7**
Fits patient expectations: is likely to fit in with patient expectations			**7**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**5**
Requires organisational change: requires changes in the way care is organised or additional resources			**6**
Requires changed routines: requires changes to fixed routines or habits			**6**
High profile: has a high profile in educational programmes or the media			**5**
Complex: is complex and requires many steps to do or organise			**2**
Trialable: can be tried out and discarded easily			**2**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**1**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
51. Patients requesting sterilisation in association with pregnancy should be informed that this increases the failure rate at least three-fold. This warning should be documented in the case notes.	29 (5/17)	50 (5/10)	**+21**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**8**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**8**
Compatible: compatible with clinicians' current norms and values in practice			**7**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**7**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**8**
Fits patient expectations: is likely to fit in with patient expectations			**5**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**3**
Requires organisational change: requires changes in the way care is organised or additional resources			**1**
Requires changed routines: requires changes to fixed routines or habits			**5**
High profile: has a high profile in educational programmes or the media			**3**
Complex: is complex and requires many steps to do or organise			**2**
Trialable: can be tried out and discarded easily			**5**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**1**

Endometrial assessment

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
52. Women below the age of 40, without recognised risk factors for endometrial cancer, e.g. polycystic ovarian syndrome (PCOS), obesity, family history, need not have an endometrial sample taken.	77 (871/1133)	71 (799/1126)	**-6**

Attribute	*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care	**9**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice	**8**
Compatible: compatible with clinicians' current norms and values in practice	**8**
Key feature: essential to the whole set of recommendations and to the ultimate goals	**8**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses	**9**
Fits patient expectations: is likely to fit in with patient expectations	**7**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly	**6**
Requires organisational change: requires changes in the way care is organised or additional resources	**8**
Requires changed routines: requires changes to fixed routines or habits	**1**
High profile: has a high profile in educational programmes or the media	**5**
Complex: is complex and requires many steps to do or organise	**1**
Trialable: can be tried out and discarded easily	**2**
Requires new knowledge or skills: requires the learning of new knowledge or skills	**1**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
53. Before an endometrial sample is taken, a careful examination of the abdomen and lower genital tract should be performed.	84 (1010/1199)	82 (929/1126)	**-2**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**8**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**8**
Compatible: compatible with clinicians' current norms and values in practice			**8**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**8**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**8**
Fits patient expectations: is likely to fit in with patient expectations			**2**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**6**
Requires organisational change: requires changes in the way care is organised or additional resources			**1**
Requires changed routines: requires changes to fixed routines or habits			**1**
High profile: has a high profile in educational programmes or the media			**5**
Complex: is complex and requires many steps to do or organise			**1**
Trialable: can be tried out and discarded easily			**5**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**1**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
54. A trial of medical therapy should be undertaken prior to taking an endometrial sample in pre-menopausal women with dysfunctional or intermenstrual bleeding.	32 (83/262)	33 (68/208)	**+1**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**9**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**7**
Compatible: compatible with clinicians' current norms and values in practice			**7**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**5**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**5**
Fits patient expectations: is likely to fit in with patient expectations			**5**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**5**
Requires organisational change: requires changes in the way care is organised or additional resources			**2**
Requires changed routines: requires changes to fixed routines or habits			**2**
High profile: has a high profile in educational programmes or the media			**4**
Complex: is complex and requires many steps to do or organise			**2**
Trialable: can be tried out and discarded easily			**2**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**1**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
55. Endometrial biopsy is the first line method of choice for obtaining an endometrial sample (possible methods to obtain an endometrial sample are by: Pipelle, Karmen cannula or Vabra aspiration).	44 (528/1199	41 (462/1126)	**-3**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**9**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**9**
Compatible: compatible with clinicians' current norms and values in practice			**9**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**9**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**9**
Fits patient expectations: is likely to fit in with patient expectations			**5**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**5**
Requires organisational change: requires changes in the way care is organised or additional resources			**1**
Requires changed routines: requires changes to fixed routines or habits			**2**
High profile: has a high profile in educational programmes or the media			**4**
Complex: is complex and requires many steps to do or organise			**2**
Trialable: can be tried out and discarded easily			**2**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**1**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
59. In pre-menopausal women where an endometrial biopsy is not the method of choice, a hysteroscopy plus or minus directed biopsy represents the method of choice.	4 (1/28)	7 (3/41)	**+3**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**7**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**7**
Compatible: compatible with clinicians' current norms and values in practice			**5**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**7**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**6**
Fits patient expectations: is likely to fit in with patient expectations			**7**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**2**
Requires organisational change: requires changes in the way care is organised or additional resources			**7**
Requires changed routines: requires changes to fixed routines or habits			**6**
High profile: has a high profile in educational programmes or the media			**5**
Complex: is complex and requires many steps to do or organise			**6**
Trialable: can be tried out and discarded easily			**2**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**6**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
60. When a D&C is performed, it should be carried out as a day case procedure unless there are medical, social or geographic contra-indications.	67 (402/600)	66 (380/571)	**-1**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**9**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**9**
Compatible: compatible with clinicians' current norms and values in practice			**9**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**9**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**9**
Fits patient expectations: is likely to fit in with patient expectations			**5**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**7**
Requires organisational change: requires changes in the way care is organised or additional resources			**1**
Requires changed routines: requires changes to fixed routines or habits			**1**
High profile: has a high profile in educational programmes or the media			**5**
Complex: is complex and requires many steps to do or organise			**1**
Trialable: can be tried out and discarded easily			**2**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**1**

The management of infertility in a hospital setting

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
61. The investigation of infertility should involve both partners from the outset.	63 (951/1510)	74 (799/1080)	**+11**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**8**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**9**
Compatible: compatible with clinicians' current norms and values in practice			**7**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**8**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**8**
Fits patient expectations: is likely to fit in with patient expectations			**5**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**6**
Requires organisational change: requires changes in the way care is organised or additional resources			**2**
Requires changed routines: requires changes to fixed routines or habits			**3**
High profile: has a high profile in educational programmes or the media			**7**
Complex: is complex and requires many steps to do or organise			**2**
Trialable: can be tried out and discarded easily			**2**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**2**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
63. Diagnostic laparoscopy and dye transit, rather than HSG, should be the primary investigation of the female genital tract.	85 (1284/1510)	79 (853/1080)	**-6**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**8**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**9**
Compatible: compatible with clinicians' current norms and values in practice			**9**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**8**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**7**
Fits patient expectations: is likely to fit in with patient expectations			**5**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**5**
Requires organisational change: requires changes in the way care is organised or additional resources			**2**
Requires changed routines: requires changes to fixed routines or habits			**3**
High profile: has a high profile in educational programmes or the media			**3**
Complex: is complex and requires many steps to do or organise			**2**
Trialable: can be tried out and discarded easily			**2**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**2**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
64. The female partner's rubella status should be checked.	45 (680/1510)	57 (616/1080)	**+12**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**9**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**9**
Compatible: compatible with clinicians' current norms and values in practice			**7**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**7**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**8**
Fits patient expectations: is likely to fit in with patient expectations			**6**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**1**
Requires organisational change: requires changes in the way care is organised or additional resources			**2**
Requires changed routines: requires changes to fixed routines or habits			**7**
High profile: has a high profile in educational programmes or the media			**3**
Complex: is complex and requires many steps to do or organise			**2**
Trialable: can be tried out and discarded easily			**5**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**2**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
65. A mid luteal plasma progesterone level should be checked in a regularly menstruating female as the basic test of ovulation.	80 (798/992)	78 (548/704)	**-2**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**9**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**9**
Compatible: compatible with clinicians' current norms and values in practice			**8**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**9**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**9**
Fits patient expectations: is likely to fit in with patient expectations			**8**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**7**
Requires organisational change: requires changes in the way care is organised or additional resources			**2**
Requires changed routines: requires changes to fixed routines or habits			**2**
High profile: has a high profile in educational programmes or the media			**6**
Complex: is complex and requires many steps to do or organise			**2**
Trialable: can be tried out and discarded easily			**6**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**2**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
66. A plan of investigation with a specific end-point should be set down in the notes and made clear to the couple concerned.	94 (1419/1510)	94 (1013/1080)	**0**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**8**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**8**
Compatible: compatible with clinicians' current norms and values in practice			**7**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**8**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**8**
Fits patient expectations: is likely to fit in with patient expectations			**8**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**6**
Requires organisational change: requires changes in the way care is organised or additional resources			**2**
Requires changed routines: requires changes to fixed routines or habits			**6**
High profile: has a high profile in educational programmes or the media			**6**
Complex: is complex and requires many steps to do or organise			**4**
Trialable: can be tried out and discarded easily			**8**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**2**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
67. The female partner should be advised to take folic acid supplements while attempting to become pregnant (0.4-0.5 mg daily).	14 (211/1510)	43 (463/1080)	**+29**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**9**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**9**
Compatible: compatible with clinicians' current norms and values in practice			**8**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**8**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**9**
Fits patient expectations: is likely to fit in with patient expectations			**7**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**4**
Requires organisational change: requires changes in the way care is organised or additional resources			**1**
Requires changed routines: requires changes to fixed routines or habits			**2**
High profile: has a high profile in educational programmes or the media			**7**
Complex: is complex and requires many steps to do or organise			**1**
Trialable: can be tried out and discarded easily			**8**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**1**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
68. A pelvic examination of the female partner should be performed.	58 (1510)	71 (770/1080)	**+13**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**9**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**9**
Compatible: compatible with clinicians' current norms and values in practice			**8**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**7**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**5**
Fits patient expectations: is likely to fit in with patient expectations			**8**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**2**
Requires organisational change: requires changes in the way care is organised or additional resources			**1**
Requires changed routines: requires changes to fixed routines or habits			**2**
High profile: has a high profile in educational programmes or the media			**3**
Complex: is complex and requires many steps to do or organise			**1**
Trialable: can be tried out and discarded easily			**2**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**1**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
69. Temperature charts are of limited use and couples should be discouraged from keeping them.	99 (1495/1510)	99 (1074/1080)	**0**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**8**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**9**
Compatible: compatible with clinicians' current norms and values in practice			**9**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**7**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**6**
Fits patient expectations: is likely to fit in with patient expectations			**4**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**7**
Requires organisational change: requires changes in the way care is organised or additional resources			**1**
Requires changed routines: requires changes to fixed routines or habits			**1**
High profile: has a high profile in educational programmes or the media			**5**
Complex: is complex and requires many steps to do or organise			**2**
Trialable: can be tried out and discarded easily			**5**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**1**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
71. The initial investigation of the male partner should include two semen analyses at least one month apart.	57 (869/1510)	60 (652/1080)	**+3**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**8**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**9**
Compatible: compatible with clinicians' current norms and values in practice			**7**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**8**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**8**
Fits patient expectations: is likely to fit in with patient expectations			**5**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**6**
Requires organisational change: requires changes in the way care is organised or additional resources			**2**
Requires changed routines: requires changes to fixed routines or habits			**2**
High profile: has a high profile in educational programmes or the media			**5**
Complex: is complex and requires many steps to do or organise			**2**
Trialable: can be tried out and discarded easily			**6**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**2**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
72. Counselling by trained counsellors should be available to all couples.	16 (241/1510)	37 (398/1080)	**+21**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**8**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**7**
Compatible: compatible with clinicians' current norms and values in practice			**3**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**6**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**7**
Fits patient expectations: is likely to fit in with patient expectations			**6**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**2**
Requires organisational change: requires changes in the way care is organised or additional resources			**9**
Requires changed routines: requires changes to fixed routines or habits			**9**
High profile: has a high profile in educational programmes or the media			**5**
Complex: is complex and requires many steps to do or organise			**8**
Trialable: can be tried out and discarded easily			**2**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**5**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
73. Drug treatments are ineffective in the treatment of idiopathic male infertility and should not be used.	96 (1454/1510)	99 (1065/1080)	**+3**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**8**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**9**
Compatible: compatible with clinicians' current norms and values in practice			**8**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**8**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**8**
Fits patient expectations: is likely to fit in with patient expectations			**3**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**3**
Requires organisational change: requires changes in the way care is organised or additional resources			**1**
Requires changed routines: requires changes to fixed routines or habits			**1**
High profile: has a high profile in educational programmes or the media			**5**
Complex: is complex and requires many steps to do or organise			**1**
Trialable: can be tried out and discarded easily			**2**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**1**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
74. The post coital test should not be used in the routine investigation of the infertile couple.	98 (1488/1510)	98 (1054/1080)	**0**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**8**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**9**
Compatible: compatible with clinicians' current norms and values in practice			**7**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**7**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**8**
Fits patient expectations: is likely to fit in with patient expectations			**7**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**2**
Requires organisational change: requires changes in the way care is organised or additional resources			**1**
Requires changed routines: requires changes to fixed routines or habits			**1**
High profile: has a high profile in educational programmes or the media			**4**
Complex: is complex and requires many steps to do or organise			**1**
Trialable: can be tried out and discarded easily			**2**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**1**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
75. Investigation of the female genital tract should not be performed in patients with oligomenorrhoea until they have had 6 months of ovulatory cycles in response to clomiphene, except where the history or examination is suggestive of tubal damage.	56 (42/75)	51 (30/59)	**-5**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**8**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**8**
Compatible: compatible with clinicians' current norms and values in practice			**8**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**8**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**8**
Fits patient expectations: is likely to fit in with patient expectations			**5**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**4**
Requires organisational change: requires changes in the way care is organised or additional resources			**1**
Requires changed routines: requires changes to fixed routines or habits			**6**
High profile: has a high profile in educational programmes or the media			**5**
Complex: is complex and requires many steps to do or organise			**2**
Trialable: can be tried out and discarded easily			**6**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**2**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
76. Drug treatments for endometriosis in women with this condition and infertility do not improve conception rates and should not be prescribed for this purpose.	56 (99/176)	66 (64/98)	**+10**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**8**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**8**
Compatible: compatible with clinicians' current norms and values in practice			**8**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**8**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**8**
Fits patient expectations: is likely to fit in with patient expectations			**3**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**3**
Requires organisational change: requires changes in the way care is organised or additional resources			**2**
Requires changed routines: requires changes to fixed routines or habits			**2**
High profile: has a high profile in educational programmes or the media			**6**
Complex: is complex and requires many steps to do or organise			**1**
Trialable: can be tried out and discarded easily			**2**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**2**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
77. A general examination of both partners should be performed.	25 (377/1510)	41 (441/1080)	**+16**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**7**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**8**
Compatible: compatible with clinicians' current norms and values in practice			**3**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**5**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**6**
Fits patient expectations: is likely to fit in with patient expectations			**5**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**2**
Requires organisational change: requires changes in the way care is organised or additional resources			**4**
Requires changed routines: requires changes to fixed routines or habits			**8**
High profile: has a high profile in educational programmes or the media			**3**
Complex: is complex and requires many steps to do or organise			**2**
Trialable: can be tried out and discarded easily			**2**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**2**

Audit criterion	*% pre-intervention compliance (number of cases assessed)*	*% post-intervention compliance (number of cases assessed)*	*% change in compliance*
78. A genital examination of the male partner should be performed.	23 (342/1510)	33 (361/1080)	**+10**
Attribute			*Final consensus panel rating*
Addresses common issue: concerned with a common clinical issue or a decision important in daily care			**7**
Precisely described: provides a sufficiently detailed and precise guide to clinical practice			**8**
Compatible: compatible with clinicians' current norms and values in practice			**2**
Key feature: essential to the whole set of recommendations and to the ultimate goals			**4**
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or meta-analyses			**6**
Fits patient expectations: is likely to fit in with patient expectations			**4**
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly			**1**
Requires organisational change: requires changes in the way care is organised or additional resources			**6**
Requires changed routines: requires changes to fixed routines or habits			**9**
High profile: has a high profile in educational programmes or the media			**2**
Complex: is complex and requires many steps to do or organise			**2**
Trialable: can be tried out and discarded easily			**3**
Requires new knowledge or skills: requires the learning of new knowledge or skills			**2**

Appendix 3A

Telephone questionnaire to doctors and midwives on knowledge of CEMD Report recommendations

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1. Identity number allocated		[ ]
2. Hospital	[	]
3. Date of interview	[/ /	]
4. Name	[	]
5. Job title	Consultant	[ ]
	Associate specialist	[ ]
	Specialist registrar	[ ]
	Senior house officer (years 1-2)	[ ]
	Senior house officer (year 3 or above)	[ ]
	Midwifery sister (labour ward)	[ ]
	Staff midwife (labour ward)	[ ]
	Midwifery sister (ANC)	[ ]
	Staff midwife (ANC)	[ ]

- *I am conducting a telephone survey on behalf of the Scottish Programme for Clinical Effectiveness in Reproductive Health. The survey involves taking a random sample of on-call obstetricians and duty midwives from across Scotland. We are specifically interested in the Confidential Enquiry into Maternal Deaths and how much staff 'on the frontline' actually know about its key recommendations.*
- *Using a telephone questionnaire because if we used a postal survey, being good professionals, staff would read up on the best answers to the questions before replying.*
- *This survey will take no longer than 5-10 minutes, does NOT test individual competence and is in complete CONFIDENCE*
- *Therefore, the most honest answers which reflect everyday practice are the most helpful*
- *We can call back at a more convenient time if appropriate*

6. Agrees to respond Yes [ ] No [ ]

Count those who say 'no' as non-responders. If unable to respond at time of first contact, note follow up arrangements

S/he will call us back later

Date: Time:

We can call her/him back later

Date: Time: Bleep: Tel:

7. Are you aware of the latest Report on Confidential Enquiries into Maternal Deaths in the UK 1994-6? (entitled *Why Mothers Die*)?

Yes [ ] No [ ]

8. Have you received a copy of the...

a. Full report? Yes [ ] No [ ]

b. Executive summary? Yes [ ] No [ ]

9. Have you read a copy of the...

a. Full report? Yes, all or most [ ] Yes, some [ ] No [ ]

b. Executive summary? Yes, all or most [ ] Yes, some [ ] No [ ]

---

10. The next question is probably the most difficult and is about how easily you can remember recommendations from the last report. As a general reminder the report covers in detail:

- Certain conditions which place mothers at higher risk of death
- Factors which contribute to sub-optimal care
- Recommendations about individual patient care
- Recommendations about the way local obstetric care is organised

Move to next page now

Without any prompting, can you recall **any three key or more** recommendations from the report?

Tick boxes against issues raised by the respondent (and according to how precise or vague their response is)

	Direct HIT	**Near MISS**
a. Recognition of main direct causes of death	[ ]	[ ]
b. Importance of prompt diagnosis or referral of suspected serious disease	[ ]	[ ]
c. Identification of women at risk of postnatal mental illness or self harm during antenatal care	[ ]	[ ]
d. Enquiry about domestic violence	[ ]	[ ]
e. Education of women about the use of seatbelts	[ ]	[ ]
f. Education of women about symptoms associated with pre-eclampsia	[ ]	[ ]
g. Education of women about first aid of epileptic fits	[ ]	[ ]
h. Early attention to chest or leg symptoms to exclude presence of thromboembolism	[ ]	[ ]
i. Management of eclampsia or pre-eclampsia by a single senior clinician	[ ]	[ ]
j. Pregnancy testing considered in any woman with unexplained abdominal pain	[ ]	[ ]
k. Prompt management of suspected ectopic pregnancy	[ ]	[ ]
l. Assessment of risk factors in considering prophylaxis against thromboembolism in all women undergoing caesarean section	[ ]	[ ]
m. Use of prophylactic antibiotics in caesarean section	[ ]	[ ]
n. Awareness of puerperal sepsis	[ ]	[ ]
o. Participation in confidential enquiries	[ ]	[ ]
p. Consultant attendance or appropriate delegation in emergencies	[ ]	[ ]
q. Need for units to have protocols for massive haemorrhage or pulmonary embolism	[ ]	[ ]
r. Unit "fire drills" for emergencies	[ ]	[ ]
s. Other recommendations not mentioned above (please specify):	[ ]	[ ]

_____

If in doubt whether response fits with any of the above, make a note and we will make a formal decision later.

_____

The following two questions are concerned with the most common causes of maternal death.

11. In the report, direct deaths are those directly due to pregnancy. Can you name the three most common causes of maternal death (starting with the most common)?

(Interviewer to write order in which causes are cited in boxes, e.g. if thromboembolism mentioned as the most common, mark "1"; and "2" for the next most common, etc.)

a. Thromboembolism [ ]

b. Pregnancy induced hypertension [ ]

c. Amniotic fluid embolus [ ]

d. Early pregnancy problems (e.g. ectopic pregnancy) [ ]

e. Sepsis (or infection) [ ]

f. Haemorrhage [ ]

g. Uterine rupture [ ]

h. Fatty liver of pregnancy [ ]

i. Anaesthesia [ ]

j. Others named: [ ]

12. In the report, indirect deaths are those due to pre-existing illness aggravated by pregnancy. Can you name the three most common causes of maternal death (starting with the most common)?

(Interviewer to write order in which causes are cited in boxes, e.g. if cardiac disease mentioned as the most common, mark "1"; and "2" for the next most common, etc.)

a. Cardiac disease [ ]

b. Epilepsy [ ]

c. Psychiatric illness [ ]

d. Others named: [ ]

13. The following questions are concerned with antenatal care. Are you usually involved in providing antenatal care?

Yes [ ] No [ ]

If no, miss this section and go to question 17.

14. Do you usually **enquire about *or* check** any of the following at booking clinics?

	Usually	If indicated	Not usually
a. Previous psychiatric disorders	[ ]	[ ]	[ ]
b. Episodes of self-harm	[ ]	[ ]	[ ]
c. Domestic violence	[ ]	[ ]	[ ]
d. Substance abuse	[ ]	[ ]	[ ]
e. Alcohol intake	[ ]	[ ]	[ ]

15. Do you discuss any of the following issues at clinics (or antenatal classes)?

	Usually	If indicated	Not usually
a. Correct use of seatbelts in pregnancy	[ ]	[ ]	[ ]
b. Advice on recognising symptoms of pre-eclampsia in early pregnancy	[ ]	[ ]	[ ]
c. Advice on safety to women with with epilepsy	[ ]	[ ]	[ ]

16. What advice about personal safety, if any, would you offer to women with epilepsy in pregnancy?

Allow respondent to volunteer advice usually given and tick relevant box.

a. Not bathing alone, or taking a shower instead [ ]

b. That relatives or friends know what to do in case of a fit [ ]

(Do not accept 'not being alone' or 'not sleeping alone' etc.)

17. Which of the following investigations are safe to conduct in pregnancy?

a. VQ scans in women with symptoms or signs suggestive of DVT or pulmonary embolism

Yes [ ] No [ ] Don't know [ ]

b. Chest x-ray in pregnant women with chest pain

Yes [ ] No [ ] Don't know [ ]

18. The following questions are concerned with guidelines and policies in your maternity unit. Are you **aware** of local policies on the following topics? And, if yes, have you received a copy or are they readily available (e.g. in labour rooms)?

	Yes – readily available or have seen	Yes – but have NOT seen	No (or don't know)
a. Management of pre-eclampsia / eclampsia	[ ]	[ ]	[ ]
b. Management of obstetric haemorrhage	[ ]	[ ]	[ ]
c. Use of thromboprophylaxis	[ ]	[ ]	[ ]
d. Antibiotic cover for caesarean sections	[ ]	[ ]	[ ]
e. Management of women who decline blood products, e.g. Jehovah's Witnesses	[ ]	[ ]	[ ]
f. Investigation and management of ectopic pregnancy	[ ]	[ ]	[ ]

19. Are you aware of the following having taken place in the past 6 months in your department? *(Tease out how interactive any educational session attended was.)*

	Yes: attended locally	Yes: attended elsewhere	Yes: unable to attend	No
(Didactic) lecture on the CEMD or any important clinical aspect of the CEMD	[ ]	[ ]	[ ]	[ ]
Interactive group tutorial on the CEMD or any important clinical aspect of the CEMD	[ ]	[ ]	[ ]	[ ]
"Fire drills" to test emergency protocols	[ ]	[ ]	[ ]	[ ]

Thank you for your time. Are there any questions we can answer about the survey?

Please refrain from mentioning the exact subject of this survey to your colleagues in the near future as we wish to interview staff in the course of their usual practice.

Appendix 4A

Questionnaire used in postal survey

Scottish Obstetric Guidelines and Audit Project

Questionnaire for Obstetricians in Scotland

Clinical Practice Guidelines for four important obstetric topics as aids to patient care in Scotland were launched nationally over 1997 and 1998. These guidelines were developed by groups of obstetricians, clinical colleagues and patient representatives.

As part of the audit element of the SOGAP project, we are now trying to obtain a picture of how much practice has changed in relation to the four guideline topics since the 'pre-guideline' survey was conducted two years ago. We would much appreciate you completing the enclosed questionnaire which has sections relating to each of the four topics. Your responses will help us obtain a representative picture of 'post-guideline' practice.

Results from this survey will be presented later in 1999.

Please return your completed questionnaire in the SAE provided **within two weeks**:

General questions about the guidelines

Q.1 Do you recall receiving any guidelines from SOGAP on the following topics?

		Yes	No
a)	The preparation of the fetus for pre-term delivery		
b)	The management of mild, non-proteinuric hypertension in pregnancy		
c)	The management of pregnancy in women with epilepsy		
d)	The management of post-partum haemorrhage		

Q.2 Where are these guidelines now?

a)	On my shelf for future reference	
b)	Uncertain	
c)	Thrown away	a, b or c

Q.3 How relevant to your clinical practice did you find the guidelines?

a)	Relevant and prompted me to change some aspects of my practice	
b)	Relevant and prompted me to reconsider some aspects of my practice	
c)	Of some general interest	
d)	Of no real interest to me	
e)	A waste of paper	
		a - e
	The preparation of the fetus for pre-term delivery	
	The management of mild, non-proteinuric hypertension in pregnancy	
	The management of pregnancy in women with epilepsy	
	The management of post-partum haemorrhage	

Q.4 Did you adopt or adapt any of the guidelines for use in your department?

	Yes	No
The preparation of the fetus for pre-term delivery		
The management of mild, non-proteinuric hypertension in pregnancy		
The management of pregnancy in women with epilepsy		
The management of post-partum haemorrhage		

Q.5 Has there been any clinical audit related to any aspect of the guidelines within your department?

	Yes	No
The preparation of the fetus for pre-term delivery		
The management of mild, non-proteinuric hypertension in pregnancy		
The management of pregnancy in women with epilepsy		
The management of post-partum haemorrhage		

Section I - Preparation of the Fetus for Pre-term Delivery

Q.1 **In the course of your clinical practice, are you involved in the management of women at risk of pre-term delivery?** Tick one box only

a) Yes ☐

b) No ☐

(If No, please proceed to Section II on page 5)

Q.2 **Do you prescribe ante-natal steroids for women at risk of pre-term delivery?** Tick one box only

a) Always ☐

b) Usually ☐

c) Seldom ☐

d) Never ☐

Q.2 **If you ever prescribe antenatal steroids, what is the lowest gestation at which you would consider doing so?** Enter No. of Weeks

☐☐ completed weeks

eg: 20 completed weeks

Q.3 **If Yes, what is the highest gestation at which you would consider prescribing ante-natal steroids?** Enter No. of weeks

eg: 38 completed weeks

☐☐ Completed weeks

Q.4 **In what circumstances would you use tocolysis**? Tick one box only

a) Never ☐

b) In rare circumstances (eg to permit intra-uterine transfer to a tertiary centre or to allow a course of steroids to be administered) and for a maximum period of <48 hours ☐

c) More liberally and for periods of >48 hours ☐

d) Other, please specify ☐

Q.5 **Do you use prophylactic antibiotics in the routine management of women presenting with pre-term, pre-labour rupture of the membranes (PPROM)?** Tick one box only

a) no, I only give antibiotics if there are clinical signs of chorio-amnionitis ☐

b) yes, I use routine, prophylactic antibiotics ☐

c) I am participating in the ORACLE trial and would usually recruit women with PPROM into this trial ☐

d) other policy, please specify ☐

Q.6 **A 25 year old primigravida with insulin-dependent diabetes (IDDM) and a twin pregnancy presents with regular, painful contractions at 28 weeks gestation. Following a clinical assessment, you decide that she is at risk of delivery within the next 7 days.**

ii) Would you initiate ante-natal steroid therapy?

Tick one box only

a) Yes ☐

b) No, because I would not prescribe steroids for any patient at 28 weeks ☐

c) No, because I feel steroids are contra-indicated in IDDM. ☐

iii) If you **would** initiate steroid therapy, would you:

Tick one box only

a) initiate steroid therapy according to my usual dosage schedule ☐

b) initiate steroid therapy using a higher dose of steroids than my usual schedule ☐

c) other, please describe ☐

iv) Assuming that contractions are regular and painful, and that vaginal examination has indicated that the cervix is 50% effaced and 3cm dilated, would you commence tocolytic therapy in an attempt to delay delivery to allow steroid therapy to have an optimal effect? Tick one box only

a) Yes ☐

b) No ☐

c) Other, (please specify ☐

v) If you would use tocolysis, which drug would you use in this case? Tick one box only

a) not applicable, I would not use tocolysis ☐

b) ritodrine/terbutaline ☐

c) indomethacin ☐

d) nifedipine ☐

e) other, please specify ☐

Q.7 **A 28 year old primigravida with no relevant medical or obstetric history presents at 35 weeks gestation with PPROM.**

i) Would you initiate steroid therapy? Tick one box only

a) Yes ☐

b) No ☐

ii) Would you initiate prophylactic antibiotic therapy? Tick one box only

a) Yes ☐

b) No ☐

c) I would enter her into the ORACLE Study ☐

d) other, please specify ☐

Section II - Management of mild, non-proteinuric hypertension in pregnancy

Q.1 **In the course of your clinical practice, are you involved in providing ante-natal care?** Tick one box only

a) Yes ☐

b) No ☐

(If No, please proceed to Section III on page 12)

Q.2 **The established, UK classification of hypertensive disorders of pregnancy (ISSHP Classification of Davey and MacGillivray, 1988) requires that a diastolic BP of ≥90mmHg be sustained for at least 4 hours before "*hypertension*" is diagnosed**

If a patient attends you for routine ante-natal care and is found to have a "spot" diastolic BP of 95mmHg, but no proteinuria, how would you usually proceed? Tick one box only

a) Recheck the BP over a short period (perhaps 20 minutes) and if diastolic remains elevated, arrange further investigations including blood tests. ☐

b) Recheck the BP within a short period and, if diastolic remains elevated, make arrangements (eg repeat attendance at surgery, home visit by community midwife, attendance at hospital day care facility) for a further BP check at least 4 hours later before initiating further investigations. ☐

c) Other course of action. Please specify ☐

Q.3. **Mrs AB is a 20 year old primigravida. At 34 weeks gestation she develops gestational hypertension (diastolic BP consistently 95mmHg) but no proteinuria. At this stage would you initiate antihypertensive drug treatment**? Tick one box only

a) Yes, I would be likely to do so. ☐

b) No, I would be unlikely to do so. ☐

c) I would not initiate such treatment myself but would refer her to a colleague for advice. ☐

d) Other, please specify ☐

Q.4. **If a similar clinical picture arose at 31 weeks gestation would you initiate anti-hypertensive therapy?** Tick one box only

a) Yes, I would be likely to do so. ☐

b) No, I would be unlikely to do so ☐

c) I would refer to a colleague for advice. ☐

Q.5. **In circumstances where you do initiate antihypertensive drug treatment for women with gestational hypertension, which drug would you most often choose as your first-line agent?** Tick one box only

a) methyldopa ☐

b) labetalol ☐

c) nifedipine ☐

d) Other, please specify ☐

Q.6. **In the case of Mrs AB (a 20 year old primigravida with a diastolic BP of 95mmHg, but no proteinuria, at 34 weeks gestation), how often would you wish her to be seen for BP check and urine testing?**

Enter no. of days: eg every [1][4] days

every [ ][ ] days

OR: I would not arrange for her to be seen on an intermittent basis, I would arrange admission to hospital for assessment. Tick box ☐

Q.7. **Which investigations would you employ for the intermittent assessment of a woman such as Mrs AB (with mild gestational hypertension, but no proteinuria, remote from term)?** Tick all that apply

a) full blood count ☐
b) platelet count ☐
c) platelet volume ☐
d) proteinuria assessed by 'dipsticks' ☐
e) proteinuria assessed by 24hr collections ☐
f) urea and electrolytes ☐
g) 24 hr urine collection for creatinine clearance ☐
h) liver function tests ☐
l) serum urate ☐
j) ultrasound assessment fetal size ☐
k) serial ultrasound assessment fetal growth
l) ultrasound assessment liquor volume ☐
m) CTG recording ☐
n) umbilical artery Doppler ultrasound ☐
o) others (please list)

Q.8 **In measuring diastolic BP, do you use Korotkoff phase IV (muffling of sounds) or phase V (disappearance of sounds)?** Tick one box only

a) phase IV ☐
b) phase V ☐

Section III - Pregnancy in Women with Epilepsy

Q.1 **In the course of your clinical practice, are you ever involved in the provision of antenatal or intrapartum care for women with epilepsy?** Tick one box only

a) Yes ☐

b) No ☐

(If No, please proceed to Section IV on page 12)

Q.2 **In relation to periconceptual folic acid supplements for women with epilepsy, do you**: Tick one box only

a) advise folic acid supplements at the 0.4mg-0.65mg/day level, as for most other women ☐

b) advise folic acid supplements at the 4-5mg/day level, as for women with a previous history of neural tube defect ☐

c) although I advise **most** women to take periconceptual folic acid, I **exclude** women with epilepsy as I believe folic acid worsens seizure control ☐

d) I do not advise periconceptual folic acid supplements for any woman ☐

e) other, please specify ☐

Q.3 **In relation to the use of Vitamin K for the prevention of haemorrhagic disease of the newborn, do you**: Tick one box only

a) ensure that the babies of mothers with epilepsy receive Vitamin K 1mg at birth ☐

b) as above, but in addition treat the mother with Vitamin K 20mg orally daily from 36 weeks gestation until delivery ☐

c) Give Vitamin K to neither the mother nor the baby ☐

d) Other strategy, please specify ☐

Q.4 **In relation to breast feeding and the mother with epilepsy, do you**: Tick one box only

a) encourage and support breast feeding as for any other mother ☐

b) discourage breast feeding in women on sedative anticonvulsants ☐

c) discourage breast feeding in any mother with epilepsy ☐

d) other policy - please specify ☐

Q.5 **In providing advice on combined oral contraception (COC) for women with epilepsy, do you**: Tick all that apply

a) indicate that COC is unsuitable for any woman with epilepsy and advise non-hormonal methods ☐

b) indicate that COC is unsuitable for women on enzyme-inducing anticonvulsants (carbamazepine, phenytoin, primidone, phenobarbitone) and advise non-hormonal methods ☐

c) include COC among the contraceptive options offered to women on enzyme-inducers but encourage the use of non-hormonal methods ☐

d) when COC is chosen by a woman on an enzyme-inducing agent, advise a 50µg pill (eg Ovran) as the first-line pill ☐

e) when COC is chosen by a woman on an enzyme-inducing agent, use two lower dose pills (eg 2 x Marvelon) as first-line ☐

f) when COC is chosen by a woman on an enzyme inducer, routinely advise a regimen involving taking three or more packs of pills in succession without a pill-free interval ☐

g) other strategies, please specify ☐

Section IV - Obstetric Haemorrhage

Q.1 **In the course of your clinical practice, are you involved in the care of women in the labour ward?** Tick one box only

a) Yes ☐

b) No ☐

(If No, please return the questionnaire in the SAE provided, NOW)

Q.2 **The 1988-1990 Report on Confidential Enquiries into Maternal Deaths provided guidelines for the management of massive obstetric haemorrhage. In your recollection, which of the following recommendations are included in the guidelines**: Tick all that accord with the Confidential Enquiry Guidelines

a) Alert all of the following: anaesthetist, haematologist, blood transfusion, porters. ☐

b) A minimum of 2 units of blood should be ordered. ☐

c) Dextrans are recommended for resuscitation until blood arrives. ☐

d) At least two intravenous lines should be set up using cannulae of not less than 14 gauge. ☐

e) Blood warming equipment is unnecessary. ☐

f) Central venous pressure monitoring should immediately be set up to help ensure that therapy is safely controlled. ☐

Thank you for your time and effort. Please return your questionnaire in the SAE provided NOW. If you have any further comments about the questionnaire, or about the SOGAP project, please add them below:

Appendix 5A. Members of Steering Group for the interrupted time series analysis of the impact of national obstetric guidelines on clinical practice

Ian Greer (chairman)	Professor, Department of Obstetrics and Gynaecology, University of Glasgow, and Consultant Obstetrician and Gynaecologist, Glasgow Royal Infirmary
Robbie Foy	MRC / CSO training fellow in health services research, Scottish Programme for Clinical Effectiveness in Reproductive Health (SPCERH), University of Edinburgh
Gillian Penney	National Coordinator, SPCERH, Aberdeen Maternity Hospital, and Clinical Senior Lecturer in Obstetrics and Gynaecology, University of Edinburgh
Jeremy Grimshaw	Director of the Clinical Epidemiology Programme Ottawa Health Research Institute and Director of the and Centre for Best Practices, Institute of Population Health, University of Ottawa (Formerly: Programme Director, Health Services Research Unit (HSRU), University of Aberdeen)
Craig Ramsay	Senior Statistician, Health Services Research Unit, University of Aberdeen
Luke Vale	Research Fellow (health economics), Health Services Research Unit, University of Aberdeen
Andrew Thomson	Lecturer, Department of Obstetrics and Gynaecology, University of Glasgow, and Consultant Obstetrician and Gynaecologist, Royal Alexandra Hospital, Paisley
Doris Campbell	Consultant Obstetrician and Gynaecologist, Aberdeen Maternity Hospital
Wang Liston	Consultant Obstetrician and Gynaecologist, Edinburgh Royal Infirmary
Jennifer Comrie	Midwife, Ayrshire Central Hospital, Irvine
Nivisson Russell	Consultant Obstetrician and Gynaecologist, Ayrshire Central Hospital, Irvine
Tahir Mahmood	Consultant Obstetrician and Gynaecologist, Forth Park Hospital, Kirkcaldy

Appendix 5B. Confidential: Case identification form for mild non-proteinuric hypertension in pregnancy study

Unit number	**Assigned study number**	**INCLUSION CRITERIA: one or more of the following** (please tick any box applicable)			**EXCLUSION CRITERIA: one or more of the following** (tick any box applicable)		**INCLUDE** if *ANY* inclusion criteria met *AND* <u>*NO*</u> exclusion criteria apply (tick box)
	Sequentially from 1 to 1440; avoid duplication	Diastolic BP > or = 90mmHg	Proteinuria + or more	GP / midwife referral for possible 'hypertension'	Diastolic BP > or = 90 mmHg before 20 weeks	BP not assessed before 20 wks (e.g. if not booked by then)	

Hospital:	Year of delivery: 199_	Month of delivery:	Initials of data collector:

RECORD INCLUSION AND EXCLUSION CRITERIA FOR ALL 40 CASE NOTES ASSESSED.

IF MORE THAN 10 CASES ARE ELIGIBLE FOR DETAILED DATA COLLECTION, ONLY COLLECT DATA FROM FIRST 10 CASES.

Appendix 5C

	Month of delivery	
	Year of delivery	
1	Initials of data collector	
2	Hospital	
3	Assigned study number	

Management of mild, non-proteinuric hypertension in pregnancy

Research data collection form

Scottish Programme for Clinical Effectiveness
in Reproductive Health (SPCERH)

Any enquiries to:

Dr Robbie Foy
SPCERH
Department of Reproductive and Developmental Sciences
University of Edinburgh
37 Chalmers Street
Edinburgh EH3 9ER

Tel 0131 229 2575 x 2115
Email R.Foy@ed.ac.uk

24th September 2001

General information

4	Date of first antenatal visit (day/month/year)	/ /	4
5	Gestation at first visit	weeks	5
6	Age at first visit	years	6
7	Parity (completed pregnancies)		7
8	Parity (miscarriages and terminations of pregnancy)		8

During the period from 20 weeks gestation to the onset of labour ONLY, which of the following problems occurred?

9	Episode of diastolic BP = or > 90 mmHg	No = 0 Yes = 1		9
10	If yes, state gestation this first occurred at		Weeks	10
11	Episode of proteinuria + or greater	No = 0 Yes = 1		11
12	If yes, state gestation this first occurred at		Weeks	12
13	Which problem occurred earliest?	High diastolic BP = 1 Proteinuria = 2		13

For questions 14 to 40, only collect data for the 7 days including and following the first episode.

Blood pressure readings

14	Diastolic BP at time of initial clinical problem (first episode of raised blood pressure *or* proteinuria)		MmHg	14
15	If the diastolic 90 mmHg or greater, was it re-checked?	YES, 4 to 24 hrs later = 1 YES, < 4 hrs later = 2 Yes, timing not recorded = 3 NO or re-checked > 24 hrs = 4		15
16	If re-checked, what was the re-checked diastolic BP reading? (Use average reading if BP 'profile' taken.)		MmHg	16

Urine dipstix testing

17	What was the reading on urine dipstix at the time of this first clinical problem?	Normal or trace = 0 *(Go to Q24)* + = 1 *(Go to Q18)* ++ = 2 *(Go to Q20)* +++ = 3 *(Go to Q24)* Not recorded = 4 *(Go to Q24)*		17
18	If proteinuria of + was recorded, was the urine specific gravity (SG) measured?	No or not recorded = 0 Yes = 1		18
19	If urine specific gravity recorded, was it under 1.03 AND the pH less than 8?	No or not recorded = 0 Yes = 1		19
20	If proteinuria + or ++, was an MSU taken?	No or not recorded = 0 Yes = 1		20
21	If proteinuria + or ++, was a urinary tract infection (UTI) diagnosed? Diagnosis can be based on clinical picture AND/OR microbiology. (If MSU is negative but patient has received antibiotics, this counts as a UTI)	No or not recorded = 0 Yes = 1		21
22	If proteinuria of ++ was recorded, was it re-checked within 24 hours?	No or not recorded = 0 Yes = 1		22
23	If proteinuria of ++ was re-checked, what was the second reading?	Normal or trace = 0 + = 1 ++ = 2 +++ = 3		23

Clinical findings and management within week of first episode (excluding findings after the onset of labour)

24	Highest diastolic BP recorded within *following 6 days*	None recorded = 0 Less than 90 = 1 90 – 100 = 2 101 – 110 = 3 Greater than 110 = 4		24
25	Highest urinary protein measurement within *following 6 days*	Normal or trace = 0 + = 1 ++ = 2 +++ = 3 Over 300mg/ 24hr = 4 None recorded = 5		25
26	*Including first contact above,* total number of clinical contacts of any type during that week *Count each attendance at antenatal clinic, day case, community clinic or home visit, or admission as one contact.*			26
27	Admission as an in-patient	No *(go to Q31)* = 0 Yes, including for hypertension = 1 Yes, for labour = 2 Yes, other reason or reason not stated = 3		27
28	Date of admission		/ /	28
29	Number of nights spent in hospital *during that week (but only up until the onset of labour)*			29
30	Is there any record of a hospital obstetrician (any grade) seeing the patient during any of the above contacts?	No = 0 Yes = 1		30

	Investigations *THAT week*	Number of times performed that week	Criteria for ABNORMAL result	Tick if any abnormal	
31	Fundal height		Over or less than 3cm of week of gestation		31
32	Enquiry into fetal movements		Reduced or absent		32
33	Serum urate (or uric acid)		Outwith local reference range		33
34	Urea and electrolytes (i.e. Sodium, Potassium, Chloride, Urea)		Any outwith local reference range		34
35	Platelet count		Outwith local reference range		35
36	Liver function tests (Protein, albumin, bilirubin, AAT, ALK, GGT, LD)		Any outwith local reference range		36
37	Ultrasound scan (including any routine scans)		Any abnormality recorded in notes		37
38	Doppler ultrasound		Any abnormality recorded in notes		38
39	Antenatal CTG		Any abnormality recorded in notes		39
40	24 hour urine collection for protein estimation		If over 300 mg / 24 hrs		40

Q41 onwards concern the antenatal period from 20 weeks onwards to delivery

Anti-hypertensive therapy

	Please indicate whether any of the following anti-hypertensive treatments were prescribed	None = 0 Yes = 1		
41	Methyldopa			41
42	Labetolol			42
43	Atenolol			43
44	Hydrallazine			44
45	Other			45
46	If another drug was prescribed, please write name of drug			46
47	If treated with any of the above drugs, did hypertension (or raised blood pressure) arise before 32 weeks gestation?	No = 0 Yes = 1		47
48	First recorded diastolic BP reading in this pregnancy (including any recorded at booking or on GP referral letter)		mmHg	48
49	What was the highest diastolic BP recorded from 20 weeks gestation to the onset of labour?		mmHg	49

Delivery

50	Total number of nights spent in hospital for any reason *from 20 weeks gestation until date of delivery*			50
51	Date of delivery		/ /	51
52	Gestational age at delivery		Weeks	52
53	Induction of labour	No = 0 Yes, including for hypertension = 1 Yes, other indication = 2		53
54	Caesarean section	No = 0 Yes, including for hypertension = 1 Yes, other reason = 2		54
55	Did the pregnancy result in a live birth?	No = 0 Yes = 1		55

Appendix 5D. Resource use and unit costs, expressed in 2001 values

Component	Resources used	Unit cost (£)
Guideline development		
Development group meetings	Four meetings lasting 4 hours each, attended by: 1 clinical research fellow 4 consultants 1 specialist registrar 2 senior midwives 1 GP	 £37.11 per hour £57.60 per hour £37.11 per hour £11.42 per hour £73.48 per hour
Travel	Nine guideline development group members to 4 meetings	£30 per person per meeting
Writing up	Twelve weeks of clinical research fellow time (40 hours per week)	£37.11 per hour
Peer review	Review for 3 hours by: 2 consultants 1 GP 2 senior midwives	 £57.60 per hour £73.48 per hour £11.42 per hour
Dissemination		
National launch meeting		
Planning	Clinical research fellow time for 40 hours	£37.11 per hour
Catering	Lunch for 87 participants	£7 per person
Participants	Meeting for 7 hours by: 44 consultants 5 senior registrars 20 senior midwives 3 GPs 3 health service managers	 £57.60 per hour £37.11 per hour £11.42 per hour £73.48 per hour £25.75 per hour
Audit and feedback		
Planning	Clinical research fellow time for 40 hours	£37.11 per hour
Survey	Photocopying and postage of 160 questionnaires (10 pages each). Twenty minutes to complete questionnaire by: 80 consultants 51 senior registrars	£0.05 per page £0.19 per envelope £57.60 per hour £37.11 per hour
Feedback	Clinical research fellow time for 40 hours Printing of 7,700 4-sided feedback sheets	£37.11 per hour £0.20 per sheet
Distribution of guideline		
Printing	Printing of 7,700 guidelines	£0.67 per guideline
Postage	Postage to 7,700 professionals	£0.24 per professional

Appendix 5E. Categorisation of outcomes

1 Descriptive data

Purpose of analysis

- To assess how many cases per unit and per month we have available for analysis
- To describe any trends and variations in demography and casemix over time and among the four hospitals
- To help assess generalisability of findings

All of the following will therefore be described by hospital and by month of year

Descriptive data	*Analysis*	*Comments*
Number of cases for each month	Frequency of deliveries per month by year *(first two items on database)*	
Number of cases for each month by hospital	Frequency of deliveries per month by year and 2(hospital)	
Age at first visit	6(age)	
Parity (completed pregnancies)	7(parity completed)	
Parity (miscarriages and terminations of pregnancy)	8(parity not completed)	
Gestation at delivery	52(gestational age)	
Recorded episodes of raised diastolic BP = or > 90 mmHg	9(diastolic over 90)	Data collectors extracted data on *up to 10 cases* per month. This will tend to under-estimate number of cases in months where more cases were found. More data available from case identification sheets held by local data collectors
Recorded episodes of proteinuria + or greater	11(proteinuria)	Ditto

2 Compliance with guideline recommendations

2.1 Appropriate diagnosis of mild, non-proteinuric hypertension

Two criteria to be met:

- Confirmation of mild hypertension by checking two BP measurements 4 – 24 hours apart;
- Investigation of '+' proteinuria by checking urine specific gravity and investigating for infection.

Recommendation	*Analysis*	*Comments*
Confirmation of mild hypertension by checking two BP measurements 4 – 24 hours apart	Proportion of cases with raised BP with documented, appropriate re-checking **A. Mild or spot hypertension** Denominator: 9(diastolic over 90) = 1 and 13(earliest problem) = 1 or 0 and 14(diastolic BP) < 110 Numerator: 15(re-checked BP) = 1, 2 or 3 *AND* **B. Severe hypertension** Denominator: 9(diastolic over 90) = 1 and 13(earliest problem) = 1 or 0 and 14(diastolic BP) > or = 110 Numerator: 15(re-checked BP) = 0, 1, 2, 3 or 4 (i.e. severe hypertension does not need to be re-checked) ADD BOTH SUBSETS TOGETHER FOR FINAL PROPORTION	The criterion of documenting re-checking over 4-24 hours later might be too strict, i.e. many women will have their BPs re-checked within 4 hours, including assessment in day care. Therefore, we have allowed ANY check as appropriate for the numerator, i.e. 15(re-checked) = 1, 2 or 3
Investigation of '+' proteinuria by checking urine specific gravity and investigating for infection (STRICT INTERPRETATION)	Proportion of cases with proteinuria + and SG checked Denominator: 11(proteinuria) = 1 and 13 (earliest problem) = 2 or 0 Numerator: Proteinuria + 17(first urine dipstix) = 1 and 18(SG measured) = 1	Insisting upon checking of SG is likely to result in no women with proteinuria being categorised as appropriately diagnosed (since SG was measured so infrequently)

Investigation of '+' proteinuria by checking urine specific gravity and investigating for infection (RELAXED INTERPRETATION)	Proportion of cases with + or greater proteinuria appropriately investigated Denominator: 11(proteinuria) = 1 and 13 (earliest problem) = 2 or 0 Numerators: **Proteinuria +** 17(first urine dipstix) = 1 and 20(MSU taken) = 1 or 21(UTI) = 1 **Proteinuria ++** 17(first urine dipstix) = 2 and 22(re-check proteinuria) = 1 **Proteinuria +++** 17(first urine dipstix) = 3 Then add up numerators and divide by denominator	Relaxed interpretation justifiable as (to the best of our knowledge) no one measured SG. Subsequent diagnostic work-up of proteinuria +++ not specified.

Comment

- For the majority of cases, these should be mutually exclusive, i.e. women will have been assessed for a raised DBP or proteinuria. To assess compliance with the guideline, we simply need to add together the numerators and denominators.
- For a subset of cases, raised BP and proteinuria may have occurred at the same time – probably detected in database by:

  10 (gestation of DBP) = 12(gestation of proteinuria)

- For these cases, the numerator will require compliance for investigation of both hypertension and proteinuria as defined above.

2.2 Management of women with a confirmed diagnosis of mild, non-proteinuric hypertension

2.2.1 The denominator

The analysis of appropriate management begins by categorising cases for the denominator according to the diagnostic groups (or levels of care) defined by the guideline.

Diagnostic group and recommended level of care	*Analysis*	*Comments*
Routine antenatal care 'Spot' hypertension not sustained on assessment And no significant proteinuria (< or = +)	9(diastolic over 90) = 1 and 13(earliest problem)= 1 or 0 and 16(re-checked BP) < 90 OR 11(proteinuria) = 1 and 13(earliest problem) = 2 or 0 and 16(re-checked BP) < 90 and either of 17(first urine dipstix) = 0 or 1 or 17(first urine dipstix) = 2 and 21(UTI diagnosed) = 1 or 23(rechecked reading) = 0 or 1	This does not include strict criterion for re-checking DBP 4-24 hours later The final section of this algorithm is complex because of the need to exclude significant proteinuria (i.e. persisting ++)
Basic surveillance Confirmed mild hypertension with no (significant) proteinuria and no abnormal findings on investigation	16(re-checked BP) between 90 and 100 inclusive AND either of 17(first urine diptix) = 0 or 1 or 17(first urine diptix) = 2 and 21(UTI diagnosed) = 1 or 23(rechecked reading) = 0 or 1 AND 24(highest DBP) = 0, 1 or 2 AND 25(highest protein) = 0, 1 or 5 AND No abnormal test, i.e. all of following = 0 31b(fundal height) 32b(fetal movements) 33b(urate) 34b(U&E) 35b(platelets) AND 49(highest DBP) minus 48 (first DBP) < 25	This does not include strict criterion for re-checking DBP 4-24 hours later Risk of relying upon normal findings on investigation is risk of spurious false positives – leading to too many women being categorised under basic surveillance. This might be a risk for U&E results. If this appears to be a frequent problem, we could take one or two variables out.

Enhanced surveillance Diastolic BP sustained at over 100mmHg or with mild hypertension and an incremental rise more than 25 mmHg since booking, clinical suspicion of poor fetal or maternal well-being or abnormal results on basic surveillance blood tests	Any one of • 16(re-checked DBP) between 101 and 110 inclusive or • 24(highest DBP) = 3 or • 16(re-checked DBP) between 90 and 110 and 49(highest DBP) minus 48 (first DBP) > or = 25 or • Any abnormality on investigation; one of following = 1 31b(fundal height) 32b(fetal movements) 33b(urate) 34b(U&E) 35b(platelets)	Remember to review potential false positives on investigation (e.g. for U&Es)
	AND either of 17(first urine diptix) = 0 or 1 or 17(first urine diptix) = 2 and 21(UTI diagnosed) = 1 or 23(rechecked reading) = 0 or 1 AND No abnormal test; all of following = 0 36b(LFTs) 37b(ultrasound) 38b(doppler) 39b(CTG)	
Specialist care	**Any one of** • 14(diastolic BP) > or = 110 • 16(re-checked BP) > or = 110 • 24(highest DBP) =4 • 17(first urine diptix) =2 and 21(UTI diagnosed) =0 or 23(re-checked reading) =2 or 3 • 17(first urine diptix) =3 • 16(re-checked DBP) between 90 and 109 *and* any abnormal test; one of following = 1 36b(LFTs) 37b(ultrasound) 38b(doppler) 39b(CTG)	

2.2.2 The numerators

Care package	*Analysis*	*Comments*
Routine antenatal care **Guideline recommended components** Not specified – but implicitly absence of unnecessary visits and investigations	For compliance, 2 OUT OF 3 criteria for contacts, admissions and investigations must be met. VISITS: Absence of unnecessary visits, i.e. either 26(total contacts) = 1 or 2 ADMISSIONS: avoidance of admissions, i.e. 27(IP admission) = 0 or 2 INVESTIGATIONS: avoidance of investigations All of following = 0 33a(serum urate) 34a(U&Es) 35a(platelets) Can also = 1 36a(LFTs) 37a(ultrasound) 38a(doppler) 39a(CTG)	For some women, the visits to ANC and day care for re-checking of BP on the same day were counted as 'two contacts' during data collection. Allowing two contacts *may* be appropriate but could over-estimate compliance. Is there a risk that platelets might be measured as part of FBC for women with anaemia. Therefore, including platelets here might underestimate compliance. For similar reasons, ultrasound, Doppler and CTGs could be excluded later from this list of investigations.

Basic surveillance **Guideline recommended components** BP recording and urine 'dipstix' twice weekly; clinical appraisal of fetal size and well-being; single estimate of serum urate, urea and electrolytes, full blood count, platelets	For compliance, 3 OUT OF 4 criteria for contacts, admissions, investigations and treatment must be met. CONTACTS: Twice weekly BP recording and urine dipstix 26(total contacts) = 2 or 3 ADMISSIONS: avoidance of admissions, i.e. 27(IP admission) = 0 or 2 INVESTIGATIONS: appropriate tests *all* as follows 31a(fundal height) = 1, 2, 3 or 4 32a(fetal movements)=1,2,3or 4 33a(serum urate) = 1 34a(U&Es) = 1 35a(platelets) = 1 36a(LFTs) = 0 37a(ultrasound) = 0 38a(doppler) = 0 39a(CTG) = 0 TREATMENT: avoidance of unnecessary anti-hypertensive treatment unless arising before 32 weeks gestation or diastolic BP over 100, and appropriate treatments used (methyldopa or labetolol), i.e. 41-44 = 0 OR 47(HT before 32 weeks) = 1 and either 41(methyldopa) or 42(labetolol) = 1 OR 49(highest DBP) > 100	Need to consider ultrasound, Doppler and CTGs on list of tests. Atenolol or hydrallazine classified as unacceptable alternatives to methyldopa and labetolol

Enhanced surveillance *Guideline recommended components* BP recording and urine dipstix at least 3 times per week; weekly serum urate, U&Es, FBC, platelets, LFTs; scan assessment of fetal size and liquor volume; CTG assessment of fetal well-being	For compliance, 3 OUT OF 4 criteria for contacts, admissions, investigations and treatment must be met. CONTACTS: Thrice weekly BP recording and urine dipstix 26(total contacts) = 3 or 4 ADMISSIONS: avoidance of admissions, i.e. 27(IP admission) = 0 or 2 INVESTIGATIONS: weekly blood tests, i.e. all of 33a(serum urate) = 1 34a(U&Es) = 1 35a(platelets) = 1 36a(LFTs) = 1 and scan, i.e. 37a(ultrasound) = 1 and CTG (or other assessment of fetal well-being), i.e. either 38a(Doppler) = 1 or 39a(antenatal CTG) = 1 to 7 TREATMENT appropriate choice of anti-hypertensive treatment (methyldopa or labetolol), i.e. either 41(methyldopa) = 1, or 42(labetolol) = 1	Similar adjustments to above Presumably, Doppler counts as 'an assessment of fetal well-being.'
Specialist care **Guideline recommended components** Referral	30(s/b obstetrician) = 1	Being seen by an obstetrician is a (weak) proxy marker of an appropriate referral.

Appendix 5F. Tables describing characteristics of patients by hospital and month

NB. For the following tables, maternity unit A = AM; B = AC; C = SM; and D = FP.

Table E1. Number of patients per hospital per month

Time (months) * HOSPITAL Crosstabulation

Count

		HOSPITAL				
		AC	AM	FP	SM	Total
Time (months)	1	8	6	9	3	26
	2	9	10	9	10	38
	3	10	10	10	9	39
	4	6	6	10	9	31
	5	7	9	10	5	31
	6	9	10	10	6	35
	7	8	10	9	9	36
	8	10	10	4	6	30
	9	8	10	10	8	36
	10	9	9	7	9	34
	11	10	6	10	9	35
	12	8	8	9	10	35
	13	9	6	9	8	32
	14	9	10	10	10	39
	15	4	10	10	10	34
	16	8	10	8	10	36
	17	5	10	10	6	31
	18	6	10	10	5	31
	19	10	10	9	5	34
	20	10	7	10	7	34
	21	9	10	10	8	37
	22	9	10	10	6	35
	23	10	10	9	9	38
	24	10	10	7	9	36
	25	7	10	10	7	34
	26	10	10	10	5	35
	27	10	10	10	9	39
	28	10	10	10	9	39
	29	9	10	10	9	38
	30	10	9	10	7	36
	31	10	10	10	8	38
	32	9	10	10	10	39
	33	10	9	11	3	33
	34	6	10	10	10	36
	35	6	10	10	9	35
	36	10	9	10	9	38
Total		308	334	340	281	1263

Table E2. Mean age of women at first visit

		AC	AM	FP	SM	Total
		Age at first visit	Age at first visit	Age at first visit	Age at first visit	
		Mean	Mean	Mean	Mean	Mean
Time (months)	1.00	29.13	26.00	24.00	31.67	26.92
	2.00	24.78	23.30	24.67	30.30	25.82
	3.00	26.80	27.70	27.60	31.44	28.31
	4.00	25.33	25.67	27.80	27.56	26.84
	5.00	29.14	29.11	26.70	30.60	28.58
	6.00	28.00	28.30	28.70	31.33	28.86
	7.00	21.63	26.70	26.78	29.67	26.33
	8.00	25.20	28.20	21.00	30.00	26.60
	9.00	27.13	26.50	29.60	32.25	28.78
	10.00	26.00	28.89	27.43	28.33	27.68
	11.00	26.70	21.50	27.20	29.00	26.54
	12.00	24.00	27.63	25.67	27.20	26.17
	13.00	26.89	28.17	28.56	25.25	27.19
	14.00	27.44	28.70	22.00	29.40	26.87
	15.00	28.75	29.30	26.20	30.00	28.53
	16.00	28.13	25.30	29.38	28.50	27.72
	17.00	31.00	26.50	28.80	30.67	28.77
	18.00	25.83	23.80	29.40	30.00	27.00
	19.00	26.90	28.44	25.78	29.60	27.42
	20.00	23.90	29.86	25.80	30.86	27.12
	21.00	27.22	23.40	25.60	30.00	26.35
	22.00	28.00	22.90	26.50	28.33	26.17
	23.00	24.60	27.30	24.89	26.22	25.76
	24.00	32.10	27.70	26.43	27.33	28.58
	25.00	26.43	29.10	29.70	29.71	28.85
	26.00	29.30	26.40	28.80	29.20	28.31
	27.00	27.00	29.50	24.80	31.89	28.21
	28.00	25.00	31.40	27.30	29.89	28.36
	29.00	26.00	29.30	27.10	29.44	27.97
	30.00	25.80	28.78	27.20	25.43	26.86
	31.00	28.30	25.20	26.80	29.13	27.26
	32.00	27.00	25.70	27.20	27.90	26.95
	33.00	26.50	24.33	27.55	28.00	26.39
	34.00	26.67	26.20	25.60	32.60	27.89
	35.00	25.00	26.50	27.10	28.00	26.80
	36.00	29.40	26.11	26.80	29.78	28.03

Table E3. Mean completed parity

		AC	AM	FP	SM	Total
		Parity completed	Parity completed	Parity completed	Parity completed	
		Mean	Mean	Mean	Mean	Mean
Time (months)	1.00	1.13	.50	.33	.00	.58
	2.00	.78	.40	.56	.50	.55
	3.00	.70	1.40	1.30	.33	.95
	4.00	.33	.67	.90	.44	.61
	5.00	.86	.67	.50	.80	.68
	6.00	.89	.80	1.70	1.00	1.11
	7.00	.50	.20	.56	1.33	.64
	8.00	.60	.80	.50	.17	.57
	9.00	1.38	.40	1.20	1.25	1.03
	10.00	.67	1.00	.43	.22	.59
	11.00	.90	.00	1.00	.56	.69
	12.00	.63	.88	.33	.30	.51
	13.00	1.00	1.00	.89	.88	.94
	14.00	.89	.40	1.10	.30	.67
	15.00	.75	1.30	.70	.40	.79
	16.00	1.00	.70	.63	.80	.78
	17.00	1.80	.80	1.00	.50	.97
	18.00	1.33	.80	1.00	.60	.94
	19.00	.90	.22	.78	.40	.61
	20.00	.90	1.00	.40	1.29	.85
	21.00	.44	.10	.60	.75	.46
	22.00	.56	.50	.40	.50	.49
	23.00	.40	.50	.44	.22	.39
	24.00	.70	.20	.29	.44	.42
	25.00	.86	.50	.90	.86	.76
	26.00	.60	.20	.90	2.20	.80
	27.00	.80	.60	1.00	.67	.77
	28.00	.10	.50	.50	.11	.31
	29.00	.78	.30	.50	.89	.61
	30.00	.40	.56	.50	.29	.44
	31.00	.40	.10	.70	.00	.32
	32.00	.56	.30	.60	.70	.54
	33.00	1.00	.33	.91	.67	.76
	34.00	.83	.80	.20	1.30	.78
	35.00	1.17	.30	.60	.33	.54
	36.00	.80	.33	.80	.33	.58

Table E4. Mean parity (uncompleted pregnancies)

		AC	AM	FP	SM	Total
		Parity not	Parity not	Parity not	Parity not	
		Mean	Mean	Mean	Mean	Mean
Time (months)	1.00	.38	.33	.11	1.33	.38
	2.00	.67	.30	.22	.50	.42
	3.00	1.20	.80	.30	.22	.64
	4.00	1.00	.33	.60	.00	.45
	5.00	.57	.22	.30	1.40	.52
	6.00	.11	.80	.30	.17	.37
	7.00	.38	.30	.11	.33	.28
	8.00	.40	.60	.00	.33	.40
	9.00	.25	.30	.40	.13	.28
	10.00	.44	.33	.00	.44	.32
	11.00	.60	.17	.20	.44	.37
	12.00	.00	.50	.11	.50	.29
	13.00	.22	.50	.33	.00	.25
	14.00	.11	.60	.40	.40	.38
	15.00	.50	.40	.40	.10	.32
	16.00	.25	.70	.38	.00	.33
	17.00	1.20	.10	.40	.17	.39
	18.00	1.00	.20	.20	.40	.39
	19.00	.50	.67	.56	.00	.48
	20.00	.60	.86	.20	.71	.56
	21.00	.33	.00	.60	.13	.27
	22.00	.78	.50	.30	.50	.51
	23.00	.40	.30	.44	.11	.32
	24.00	.30	.90	.14	.44	.47
	25.00	.00	.20	.40	.71	.32
	26.00	.00	.20	.30	.60	.23
	27.00	.50	.40	.90	.33	.54
	28.00	.10	.40	.20	.78	.36
	29.00	.56	.30	.10	.22	.29
	30.00	.00	.78	.10	.71	.36
	31.00	.40	.70	.20	.13	.37
	32.00	.44	.30	.00	.40	.28
	33.00	.80	.56	.45	.67	.61
	34.00	1.33	.20	.30	.70	.56
	35.00	.33	.20	.10	.44	.26
	36.00	1.30	.22	.40	.44	.61

Table E5. Mean gestation at delivery

		AC	AM	FP	SM	Total
		Gestational age at delivery	Gestational age at delivery	Gestational age at delivery	Gestational age at delivery	
		Mean	Mean	Mean	Mean	Mean
Time (months)	1.00	39.63	39.17	40.11	37.00	39.38
	2.00	39.78	39.40	39.56	38.30	39.24
	3.00	38.70	37.70	39.60	39.22	38.79
	4.00	39.50	39.17	40.10	38.22	39.26
	5.00	38.14	39.00	39.60	37.20	38.71
	6.00	39.67	39.80	38.90	40.50	39.63
	7.00	39.63	39.30	39.89	39.56	39.58
	8.00	39.50	38.90	39.75	39.50	39.33
	9.00	37.25	39.10	40.00	39.75	39.08
	10.00	39.00	38.44	39.14	38.89	38.85
	11.00	38.80	40.00	39.50	39.22	39.31
	12.00	40.25	39.50	38.78	38.90	39.31
	13.00	39.78	39.67	39.22	38.88	39.38
	14.00	38.78	40.10	38.80	38.30	39.00
	15.00	38.50	39.00	39.60	39.70	39.32
	16.00	38.88	40.10	38.75	39.40	39.33
	17.00	39.20	39.70	39.80	39.33	39.58
	18.00	38.33	38.80	38.50	40.00	38.81
	19.00	39.30	39.00	39.33	39.20	39.21
	20.00	39.40	40.14	39.20	39.14	39.44
	21.00	39.67	39.10	39.60	39.50	39.46
	22.00	39.00	39.90	40.60	39.50	39.80
	23.00	39.80	39.50	39.56	37.44	39.11
	24.00	39.30	39.30	40.43	38.22	39.25
	25.00	38.86	39.10	39.70	37.43	38.88
	26.00	40.30	39.30	39.60	38.80	39.60
	27.00	39.50	38.30	39.20	37.89	38.74
	28.00	40.20	39.10	38.70	39.89	39.46
	29.00	39.11	39.60	38.90	38.78	39.11
	30.00	39.00	38.78	39.30	39.43	39.11
	31.00	39.70	39.70	38.80	38.88	39.29
	32.00	39.11	38.40	39.10	39.50	39.03
	33.00	40.10	39.33	38.91	38.67	39.36
	34.00	38.67	40.20	38.90	39.10	39.28
	35.00	39.67	38.70	35.70	39.44	38.20
	36.00	38.60	38.89	39.90	38.67	39.03

Table E6. Proportion of patients with raised DBP

			AC	AM	FP	SM	Total
			Mean	Mean	Mean	Mean	Mean
Time (months)	1.00	Diastolic over 90	.63	.67	.67	1.00	.69
	2.00	Diastolic over 90	.56	.90	.44	.70	.66
	3.00	Diastolic over 90	.60	.80	.60	.78	.69
	4.00	Diastolic over 90	.33	.50	.70	.78	.61
	5.00	Diastolic over 90	.43	.67	.30	.60	.48
	6.00	Diastolic over 90	.78	.90	.40	.50	.66
	7.00	Diastolic over 90	.50	.60	.56	.78	.61
	8.00	Diastolic over 90	.70	.80	.75	.83	.77
	9.00	Diastolic over 90	.75	.90	.50	.00	.56
	10.00	Diastolic over 90	.67	1.00	.57	.56	.71
	11.00	Diastolic over 90	.70	.83	.80	.56	.71
	12.00	Diastolic over 90	.63	.50	.89	.60	.66
	13.00	Diastolic over 90	.44	.67	.67	.75	.63
	14.00	Diastolic over 90	.78	.60	.40	1.00	.69
	15.00	Diastolic over 90	.50	.60	.80	.70	.68
	16.00	Diastolic over 90	.75	.60	.13	.50	.50
	17.00	Diastolic over 90	.20	.30	.60	.83	.48
	18.00	Diastolic over 90	.50	.70	.90	.20	.65
	19.00	Diastolic over 90	.60	.80	.67	.60	.68
	20.00	Diastolic over 90	.60	.43	.70	.71	.62
	21.00	Diastolic over 90	.56	.50	.70	.25	.51
	22.00	Diastolic over 90	.33	.60	.40	.83	.51
	23.00	Diastolic over 90	.50	.70	.67	.67	.63
	24.00	Diastolic over 90	.60	.50	.71	.56	.58
	25.00	Diastolic over 90	.43	.70	.90	.71	.71
	26.00	Diastolic over 90	.60	.70	.40	.80	.60
	27.00	Diastolic over 90	.40	.70	.50	.56	.54
	28.00	Diastolic over 90	.40	.50	.80	.67	.59
	29.00	Diastolic over 90	.33	.60	.70	.44	.53
	30.00	Diastolic over 90	.60	.44	.50	.43	.50
	31.00	Diastolic over 90	.30	.80	.70	.75	.63
	32.00	Diastolic over 90	.22	.60	.70	.60	.54
	33.00	Diastolic over 90	.30	1.00	.64	1.00	.67
	34.00	Diastolic over 90	.83	.70	.80	.60	.72
	35.00	Diastolic over 90	.33	.60	.60	.44	.51
	36.00	Diastolic over 90	.90	.56	.60	.78	.71

Table E7. Proportion of cases with suspected proteinuric episode

			AC	AM	FP	SM	Total
			Mean	Mean	Mean	Mean	Mean
Time (months)	1.00	Proteinuria	.50	.83	.56	.00	.54
	2.00	Proteinuria	.67	.40	.78	.70	.63
	3.00	Proteinuria	.60	.60	.50	.33	.51
	4.00	Proteinuria	.83	.67	.70	.67	.71
	5.00	Proteinuria	.71	.44	.70	.60	.61
	6.00	Proteinuria	.33	.20	.80	.50	.46
	7.00	Proteinuria	.88	.40	.56	.78	.64
	8.00	Proteinuria	.80	.50	.25	.50	.57
	9.00	Proteinuria	.63	.50	.70	1.00	.69
	10.00	Proteinuria	.56	.33	.43	.44	.44
	11.00	Proteinuria	.70	.83	.40	.78	.66
	12.00	Proteinuria	.88	.75	.11	.60	.57
	13.00	Proteinuria	.67	.33	.33	.88	.56
	14.00	Proteinuria	.44	.60	.90	.40	.59
	15.00	Proteinuria	.50	.70	.50	.40	.53
	16.00	Proteinuria	.50	.60	.88	.70	.67
	17.00	Proteinuria	.80	.80	.60	.17	.61
	18.00	Proteinuria	.67	.40	.40	.80	.52
	19.00	Proteinuria	.60	.50	.44	.40	.50
	20.00	Proteinuria	.70	.71	.50	.43	.59
	21.00	Proteinuria	.56	.70	.50	.75	.62
	22.00	Proteinuria	.78	.70	.80	.50	.71
	23.00	Proteinuria	.90	.60	.78	.56	.71
	24.00	Proteinuria	.80	.80	.71	.78	.78
	25.00	Proteinuria	.86	.60	.30	.57	.56
	26.00	Proteinuria	.70	.60	.80	.40	.66
	27.00	Proteinuria	.80	.60	.70	.78	.72
	28.00	Proteinuria	.80	.80	.80	.78	.79
	29.00	Proteinuria	.67	.60	.60	.89	.68
	30.00	Proteinuria	.70	.78	.90	1.00	.83
	31.00	Proteinuria	.90	.50	.50	.50	.61
	32.00	Proteinuria	.89	.80	.60	.60	.72
	33.00	Proteinuria	.80	.44	.45	1.00	.61
	34.00	Proteinuria	.67	.60	.30	.80	.58
	35.00	Proteinuria	.67	.70	.80	.67	.71
	36.00	Proteinuria	.40	.67	.50	.44	.50

Appendix 6A. Interview schedule for meetings with lead gynaecologists

Details of meeting

1	Gynaecology unit	
2	Lead gynaecologist	
3	Interviewers	
4	Date of meeting	

Purpose of meeting

(5-10 min)

5	Objectives of meeting • Identification of factors that might help or hinder implementation of key guideline recommendations • Identification of clinical staff for the (TPB) questionnaire survey and targeting of the intervention • Local development of the intervention	
6	Questions asked about IMPACT	

Factors that help or hinder implementation of the guideline recommendations

(5 min per recommendation; total time 30 min)

7	*Guideline recommendation*	*Unit baseline compliance*			%
	Offer of appointment with a gynaecologist within five days of referral	*Help implementation*		*Hinder implementation*	
A	**Recommendation-specific factors**	Guideline produced by professional body (RCOG)	1	Lack of evidence supporting recommendation	1
			2		2
			3		3
			4		4
B	**Individual factors**	Women seeking abortion seen as high priority	1	Women seeking abortion seen as low priority	1
			2	Lack of feedback on waiting times	2
			3	Doubt over potential benefits	3
			4	Unfamiliarity with guideline or recommendation	4
			5		5
			6		6
C	**Organisational or environmental factors**	Existing telephone referral system	1	Delay mainly caused by referrer	1
		Unit guidance or targets available	2	Insufficient resources to improve referral system / not organisational priority	2
			3	Coping with fluctuations in demand or supply (e.g. colleagues on leave)	3
			4	No unit guidance or targets	4
			5	Lack of facilities	5
			6		6
			7		7

8	*Guideline recommendation*	*Unit baseline compliance*			*%*
	Ascertainment of cervical cytology history	*Help implementation*		*Hinder implementation*	
A	**Recommendation-specific factors**	High priority given to cervical screening	1	Low priority of cervical screening in abortion care	1
		Guideline produced by professional body (RCOG)	2	Little point in asking if unable or not planning smear at clinic	2
			3		3
			4		4
B	**Individual factors**		1	Accidental omission	1
			2	Low outcome expectancy	2
			3	Low recording	3
			4		4
			5		5
C	**Organisational or environmental factors**	Expected norm	1	Not expected norm	1
		Unit guidance available	2	No unit guidance	2
			3	Insufficient time	3
			4	Women don't expect smear at clinic	4
			5		5

9	*Guideline recommendation*	*Unit baseline compliance*			*%*
	Antibiotic prophylaxis or screening for lower genital tract organisms	*Help implementation*		*Hinder implementation*	
A	**Recommendation-specific factors**	Convincing evidence base	1	Uncertainty over supporting evidence	1
		Reduction of complications	2		2
		Guideline produced by professional body (RCOG)	3		3
			4		4
B	**Individual factors**		1	Low outcome expectancy (perceived because infection is uncommon or high number needed to treat)	1
			2	(Some) patients not perceived as high risk	2
			3	Accidental omission	3
			4		4
C	**Organisational or environmental factors**	Unit guidance available	1	No unit guidance	1
		Expected local norm	2	Not expected norm	2
			3	Disruption to routine practice	3
			4		4

10	*Guideline recommendation*	*Unit baseline compliance*			*%*
	Misoprostol cost-effective alternative to gemeprost (in early medical abortion, cervical priming and mid-trimester medical abortion)	*Help implementation*		*Hinder implementation*	
A	**Recommendation-specific factors**	Convincing evidence base	1	Uncertainty over evidence base	1
		Guideline produced by professional body (RCOG)	2		2
		Fewer side effects	3		3
		Ease of storage	4		4
B	**Individual factors**	Cost-effectiveness seen as priority	1	Individual clinical autonomy (and antipathy to cost-containment)	1
			2	Greater familiarity with gemeprost	2
			3		3
			4		4
C	**Organisational or environmental factors**	Unit guidance available	1	No unit guidance	1
		Expected local norm	2	Not expected local norm	2
		Routine part of care (e.g. written up at assessment clinic)	3		3
			4		4

11	*Guideline recommendation*	*Unit baseline compliance*			%
	Offer of contraceptive supplies if required	*Help implementation*		*Hinder implementation*	
A	**Recommendation-specific factors**	Convincing evidence	1		1
		Guideline produced by professional body (RCOG)	2		2
			3		3
			4		4
B	**Individual factors**	High priority for gynaecologist	1	Low outcome expectancy	1
			2	Accidental omission	2
			3	Low priority for gynaecologist	3
			4		4
C	**Organisational or environmental factors**	Availability of one or more methods	1	Unavailability of choice of methods at discharge	1
		High priority for unit	2	Delays in obtaining supplies from pharmacy	2
		Unit guidance available	3	Low priority for unit	3
			4	Lack of shared protocol or communication with referrer	4
			5	No unit guidance	5
			6	Need for FP trained nurses	6
			7		7

12	*Guideline recommendation*	*Unit baseline compliance*			*%*
	Local selection	*Help implementation*		*Hinder implementation*	
A	**Recommendation-specific factors**		1		1
			2		2
			3		3
			4		4
B	**Individual factors**		1		1
			2		2
			3		3
			4		4
C	**Organisational or environmental factors**		1		1
			2		2
			3		3
			4		4

Identification of sampling frame for the TPB questionnaire

(Allow 10 min)

13	Staff providing abortion care	Number / location	Names (if known)
A	Consultants		
B	SpRs / associate specialists / clinical assistants		
C	SHOs		
D	Nursing and midwifery sisters		
E	Nursing and midwifery staff		

Contact details for staff lists:

The intervention

(10 – 20 min)

	Component	*Interest or planned uptake*
14	Feedback of baseline audit data	
15	**Educational meeting (including refreshments)**	
A	Presentation including • A *brief* outline of the IMPACT study • Feedback of baseline audit • The rationale behind the RCOG induced abortion guideline • The evidence supporting key recommendations	
B	Discussion of barriers and potential solutions • Feedback of barriers identified from TPB staff survey, literature review and interviews with lead gynaecologists • Breakout groups to address specific issues	
C	*Alternative*: More focused discussion with whole group agreeing and focusing on most important areas for improvement	
D	Formulation and agreement of action plan, including local target setting	
E	Production of a short local newsletter (with practical and financial support)	
F	Final / probable option selected:	One hour meeting plus follow-up Half-day workshop One hour meeting Other:
G	Provisional date(s)	
16	**Review of structured case records** Structured case record available?	
17	**Promotion of patient leaflet**	
18	**Other comments or suggestions**	

Appendix 6B. ImpACT survey of clinical staff

ImpACT (Improving Abortion Care Trial) is testing the effectiveness of a strategy to improve clinical practice in line with recommendations from the RCOG guideline, *The care of women requesting induced abortion*.

A wide range of barriers exists to the provision of optimal care, e.g. related to resources, skills or attitudes. In designing a strategy to help overcome at least some of these barriers, we will take account of previous research on how and why people change behaviour.

We therefore hope to find out about the views of medical and nursing staff involved in abortion care about two guideline recommendations using a postal questionnaire.

The questionnaire is designed to measure four things for each of the two guideline recommendations:

- People's **intentions** to follow the recommendation,
- Their **attitude** towards it,
- How much **social pressure** they feel to follow the recommendation,
- Whether they are actually **able** to follow the recommendation in their current clinical environment.

There are between three and five questions for each of these measures. Some questions may therefore appear repetitive. This is necessary because previous research has found that people respond differently to slightly different wording of the questions.

We also appreciate that you may have no direct control over whether you can actually follow all recommendations in practice. There might be a clinical action you wish to take but cannot, for example because of unit policy or because you delegate this to somebody else. This questionnaire explores this sort of issue.

This questionnaire should take no longer than 10 minutes to complete. Thank you for your time.

All responses to this survey will be treated in confidence and all results will be presented anonymously. Therefore individual staff and units will not be identified.

We have coded each questionnaire to help identify individual respondents and hospitals. This information will both help the analysis and ensure that we do not bother staff who have already completed the survey with further reminder letters.

Questionniare code			

The following questions refer to this scenario: ***Next week, a woman is referred to your clinical team by her GP requesting abortion.***

We recognise that you may or may not have much control over how soon this woman can be offered an assessment appointment. Furthermore, some units use a centralised referral system whereby GPs or family planning doctors can arrange assessment appointments for patients by telephone.

Please circle relevant response

1. Are patients referred to your unit for an assessment appointment via a centralised referral system?

Yes No Not sure

Attitudes

2. Overall, I think that offering this woman an assessment appointment within 5 days of referral would be:

Bad practice	1	2	3	4	5	6	7	Good practice
Harmful to her	1	2	3	4	5	6	7	Beneficial to her
The wrong thing to do	1	2	3	4	5	6	7	The right thing to do
Unfair to women awaiting appointments for other reasons	1	2	3	4	5	6	7	Fair

Intentions

3. I intend to offer this woman an assessment appointment within 5 days of referral

Definitely do not	1	2	3	4	5	6	7	Definitely do

4. I want to offer this woman an assessment appointment within 5 days of referral

Definitely do not	1	2	3	4	5	6	7	Definitely do

5. I plan to offer this woman an assessment appointment within 5 days of referral

Definitely do not	1	2	3	4	5	6	7	Definitely do

Social pressure

6. Most professional colleagues would offer this woman an assessment appointment within 5 days of referral

Definitely no	1	2	3	4	5	6	7	Definitely yes

7. People who are important to me think that I ...

Definitely should not	1	2	3	4	5	6	7	Definitely should

... offer this woman an assessment appointment within 5 days of referral

8. My professional body (RCOG, RCM or RCN) would ...

Definitely disapprove	1	2	3	4	5	6	7	Definitely approve

... of my offering this woman an assessment appointment within 5 days of referral

Ability

9. Offering this woman an assessment appointment within 5 days of referral is:

Difficult	1	2	3	4	5	6	7	Easy

10. What is the likelihood that you will be able to offer this woman an assessment appointment within 5 days of referral?

Very unlikely	1	2	3	4	5	6	7	Very likely

11. I am confident that I could offer an assessment appointment within 5 days of referral to this woman if I wanted to.

Strongly disagree	1	2	3	4	5	6	7	Strongly agree

12. There are factors outside my control that prevent me from offering this woman an assessment appointment within 5 days of referral

Strongly disagree	1	2	3	4	5	6	7	Strongly agree

13. How much control do you have over whether or not to offer an assessment appointment within 5 days of referral?

No control	1	2	3	4	5	6	7	Complete control

14. Please add any comments on what factors make it difficult or easy to offer an assessment appointment within 5 days of referral

Difficult:
Easy:

The following questions refer to this scenario: ***Next week, a woman is being discharged from your unit following suction termination of pregnancy. She has indicated her wish to use the oral contraceptive pill but has not already been given supplies from any source.***

We recognise that in some units nursing staff are responsible for providing contraception on discharge – if it is required.

Please circle relevant response

15. Who provides contraception at discharge on your unit?

Mainly nursing staff	Mainly medical staff	A combination of clinical staff	Contraception not routinely provided at discharge	Not sure

Attitudes

16. Overall, I think that providing contraceptive supplies to this woman prior to discharge would be:

17.

Bad practice	1	2	3	4	5	6	7	Good practice
Harmful	1	2	3	4	5	6	7	Beneficial
A waste of time	1	2	3	4	5	6	7	A good use of time
The wrong thing to do	1	2	3	4	5	6	7	The right thing to do

Intentions

18. I intend to provide contraceptive supplies for this woman prior to discharge

Definitely do not	1	2	3	4	5	6	7	Definitely do

19. I want to provide this woman with contraceptive supplies prior to discharge

Definitely do not	1	2	3	4	5	6	7	Definitely do

20. I plan to provide this woman with contraceptive supplies prior to discharge

Definitely do not	1	2	3	4	5	6	7	Definitely do

Social pressure

21. Most professional colleagues would provide this woman with contraceptive supplies prior to discharge

Definitely no	1	2	3	4	5	6	7	Definitely yes

22. People who are important to me think that I ...

Definitely should not	1	2	3	4	5	6	7	Definitely should

... provide this woman with contraceptive supplies prior to discharge

23. My professional body (RCOG, RCM or RCN) would ...

Definitely disapprove	1	2	3	4	5	6	7	Definitely approve

... of my providing this woman with contraceptive supplies prior to discharge

Ability

24. Providing this woman with contraceptive supplies prior to discharge would be:

Difficult	1	2	3	4	5	6	7	Easy

25. What is the likelihood that you will be able to provide this woman with contraceptive supplies prior to discharge?

Very unlikely	1	2	3	4	5	6	7	Very likely

26. I am confident that I could provide this woman with contraceptive supplies prior to discharge if I wanted to.

Strongly disagree	1	2	3	4	5	6	7	Strongly agree

27. There are factors outside my control that prevent me from providing this woman with contraceptive supplies prior to discharge

Strongly disagree	1	2	3	4	5	6	7	Strongly agree

28. How much control do you have over whether or not to provide contraceptive supplies prior to discharge?

Complete control	1	2	3	4	5	6	7	No control

29. Please add any comments on what factors make it difficult or easy to provide contraceptive supplies prior to discharge

Difficult:
Easy:

Appendix 6C. Feedback report

Scottish Programme for Clinical Effectiveness in Reproductive Health

Induced Abortion Care in Scotland
Baseline Audit Report

June 2001

Contents (NB. Page numbers changed from original report)

Background. Induced abortion is one of the most commonly performed gynaecological procedures, with over 12,000 undertaken annually in Scotland. In March 2000, the Royal College of Obstetricians and Gynaecologists published a clinical guideline, *The care of women requesting induced abortion*. Despite continuing improvements, standards of care still vary within and among hospitals in Scotland. The guideline aims to improve the following key aspects of care: access to care; information for women; assessment for abortion procedures; choice of procedures; and after care.

The Scottish Programme for Clinical Effectiveness in Reproductive Health (SPCERH). This professionally-led programme brings together a wide range of educational, audit and research activities that share the common aim of promoting evidence-based practice among reproductive healthcare professionals.

One of the programmes' core activities is to develop and disseminate clinical guidelines. Previous research suggests that the distribution of a clinical guideline is unlikely to change clinical practice by itself. It is therefore important to test new ways of providing support to local units to put clinical guidelines into practice.

This baseline audit represents part of a national study to improve induced abortion care. All twenty-six gynaecology units in Scotland are participating in this study. Its findings will inform SPCERH's methods of disseminating clinical guidelines in the future.

Confidentiality. Audit results relating to individual gynaecology units will remain confidential. Results on the performance of individual units are therefore presented in this report in anonymised form. Each hospital has been allocated a letter and the lead gynaecologist at each 'intervention' hospital has been informed of the letter allocated to his/her unit. Thus, staff at each gynaecology unit can view their own performance against the range of performance achieved by others.

Data collection. For the baseline audit, all women admitted for an induced abortion from 1st September to 30th November 2000 were identified locally via ward admission books or referral records. Induced abortions for fetal anomaly were excluded. Data collection was performed by local clinical or clerical staff following a standard training session.

The case note review assessed adherence to 27 out of the 57 graded recommendations made in the guideline.

A random sample of 50 cases was identified in each gynaecology unit and case notes were reviewed using a structured data collection form. All case notes were reviewed in units admitting 50 or fewer cases over this period.

A follow up case note review is scheduled to take place over a similar period in 2001. Where available, 75 case notes will be reviewed in each unit. A patient survey is provisionally scheduled to take place during September 2001.

Purposes and interpretation of feedback. This feedback aims to stimulate local discussion and help staff in individual units identify good clinical practice as well as any potential to improve care.

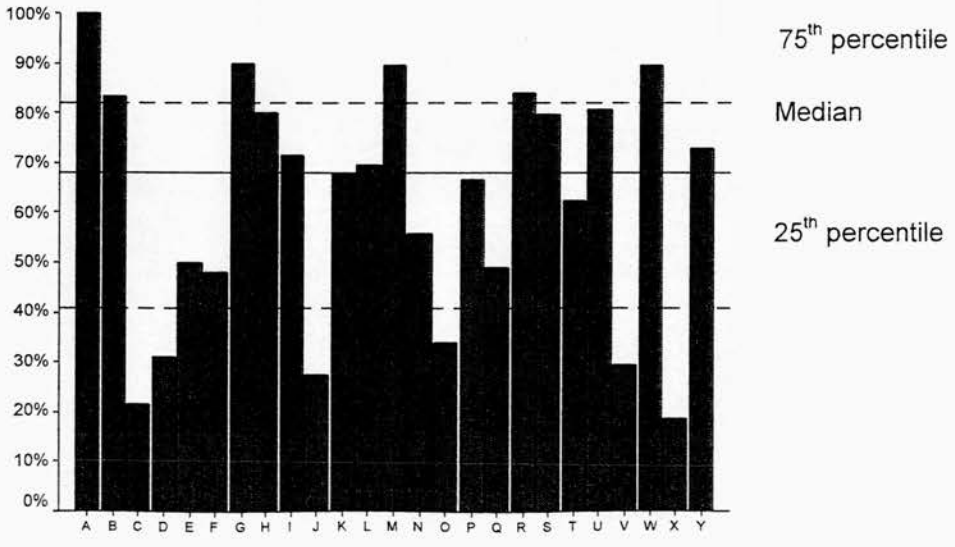
There are two general limitations to the baseline audit data. Firstly, fifty represents a relatively small sample size for audit purposes. Therefore, some of the variation between gynaecology units may be due to chance. Secondly, case note reviews may under-estimate adherence to guideline recommendations when patients *receive* care which is not *recorded* in case notes. However, for the majority of these guideline recommendations, clear recording in case notes is important, least of all for medico-legal purposes.

Local coordinators and data collectors

Hospital	Coordinator	Data collector(s)
Aberdeen Royal Infirmary	Dr Gillian Flett	Ms Frances Findlay
Ayrshire Central Hospital	Dr Nivison Russell	Sister Jackie McCallum
Borders General Hospital	Dr Roddy Campbell	Ms Marion McKenzie
Caithness General Hospital	Dr Adam Gordon	Ms Rona McLeod
Dr Gray's Hospital	Dr David Evans	Ms Jane Gray
Dumfries & Galloway Royal Infirmary	Dr Michael Geals	Sister Joanne Bradley
Falkirk & District Royal Infirmary	Dr Ken Grant	Ms Carol Davies
Forth Park Hospital	Dr Tahir Mahmood	Ms Morag Telfer
Glasgow Royal Infirmary	Dr Mary Rodger	Sister Anne Kerr
Hairmyres Hospital	Dr Keith Spowart	Staff Elizabeth Flanagan
Inverclyde Royal Hospital	Dr Jim Robins	Sister Shirley Roche
Law Hospital	Dr Chris Lennox	Sister Margaret Morgan
Monklands Hospital	Dr T Dow	Sister Anne Lawrie
Ninewells Hospital	Dr Maggie Thomson	Sister Jackie Dunlop
Perth Royal Infirmary	Dr W Phillips	Ms Fionna Clark Ms Rena McDonald
Raigmore Hospital	Dr Lucy Caird	Ms Margaret Cameron Ms Jackie Campbell Ms Margaret Williamson
Royal Alexandra Hospital	Dr Ken Muir	Ms Sandra Crawford
Edinburgh Royal Infirmary	Professor Hilary Critchley	Ms Lorraine Adamson
Southern General Hospital	Dr Bill Naismith	Sister Nicky Harvey
St John's Hospital at Howden	Dr Tara Cooper	Ms Anne Close Ms Ona Lally Ms Eleanor Swan Ms May Wynne
Stirling Royal Infirmary	Dr Wendy McMullen	Ms Alana Horsburgh
Stobhill NHS Trust	Dr Colin Forrest	Ms Margaret Burke Ms Anne Coyle
Vale of Leven Hospital	Dr Mike Haxton	Staff Elsie McKechnie
Victoria Infirmary NHS Trust	Dr Douglas Mack	Sister Victoria Morrison
Western Infirmary NHS Trust	Dr Judith Roberts	Ms Fiona McLeod
Western Isles Hospital	Dr P Sarkar	Ms Anne-Marie MacDonald

Format of feedback

Recommendation and grade	The guideline recommendations were graded as follows: **A** Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation. **B** Requires the availability of well conducted clinical studies, but no randomised clinical trials on the topic of the recommendation. **C** Requires evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates an absence of directly applicable clinical studies of good quality. Good practice points. Recommended best practice based on the clinical experience of the Guideline Development Group
Rationale	A brief summary of the rationale or supporting evidence for each recommendation.
Method of assessment	How case note data were used to measure adherence to recommendation. Number of cases relevant to recommendation. For certain recommendations, several gynaecology units had no relevant cases. Therefore, their identifying letter does not appear in subsequent bar charts or tables. No data were available for unit Z at the time of writing.
Bar chart	The horizontal axis represents each gynaecology unit in Scotland, each identified by a letter. The vertical axis represents the percentage compliance with the recommendation in the guideline. Therefore, 100% is perfect compliance with the guideline and 0% is zero compliance with the guideline. The horizontal lines on the graph represent the median compliance (solid line) and the 25th and 75th percentiles (dashed lines). The median compliance is the point at which 50% of the hospitals are above this value and 50% are below this value. The 75th percentile is the point at which 25% of the hospitals lie above this value, and the 25th percentile represents the point at which 25% of the hospitals lie below this value. The overall number of relevant cases assessed was small for several recommendations. Feedback for these recommendations is therefore presented in tabular or text format as bar charts might give a misleading impression.
Comments	Commentary on overall pattern, including average compliance and variations among gynaecology units. For five recommendations, interviews with lead gynaecologists from each unit identified factors that helped or hindered implementation.



Organisation and access

Recommendation	Service arrangements should be such that: • Ideally, all women requesting abortion are offered an assessment appointment within five days of referral • As a minimum standard, all women requesting abortion are offered an assessment appointment within two weeks of referral (Grade C)
Rationale	• The earlier in pregnancy an abortion is performed, the lower the risk of complications • Five days suggested as an appropriate target between referral and assessment by Birth Control Trust • This target also endorsed by a consensus survey of Scottish gynaecologists
Method of assessment	Proportion of patients with 5 or fewer days between date of referral (usually on general practitioner letter) and date of first gynaecology outpatient assessment appointment (Figure 1). Proportion meeting minimum standard (i.e. within 14 days) calculated similarly (Figure 2). Data available for total of 1041 cases.
Comments	Median compliance with the first recommendation was 53%, with substantial variation among gynaecology units. Most notably units C, D, J, O, V and X had problems providing assessment appointments within 5 days. In calculating adherence, no allowance was made for non-working days nor for the possibility that some women may have not have attended the first appointment offered. At least 90% of women were seen within 14 days in 15 units. Factors suggested that help meeting this recommendation: • Women seeking abortion seen as high priority • Existing telephone referral system • Regular reminders to GPs about need for prompt referral and to make use of telephone referral system • One person coordinates appointments or clinic • No limits on clinic appointments Factors suggested that hinder meeting this recommendation: • Insufficient resources to improve referral system / not organisational priority • Women seeking abortion seen as low priority (usually by some or minority of clinicians) • Limited number of consultants or juniors perform abortions • Coping with fluctuations in demand or supply (e.g. colleagues on leave, limited spaces on theatre lists) • Lack of facilities, e.g. clinic rooms, day or gynaecology beds, theatre capacity • Limit numbers to allow for adequate counselling

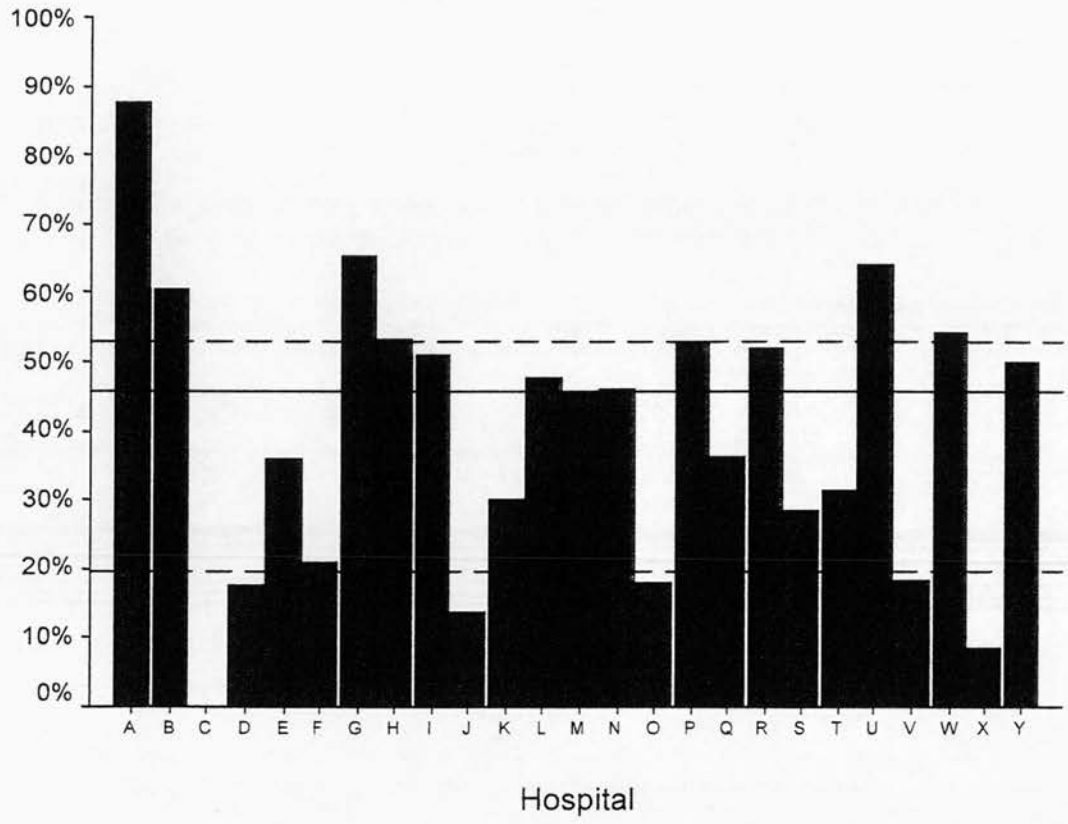


Figure 1. Percentage of women attending assessment appointment within 5 days of referral

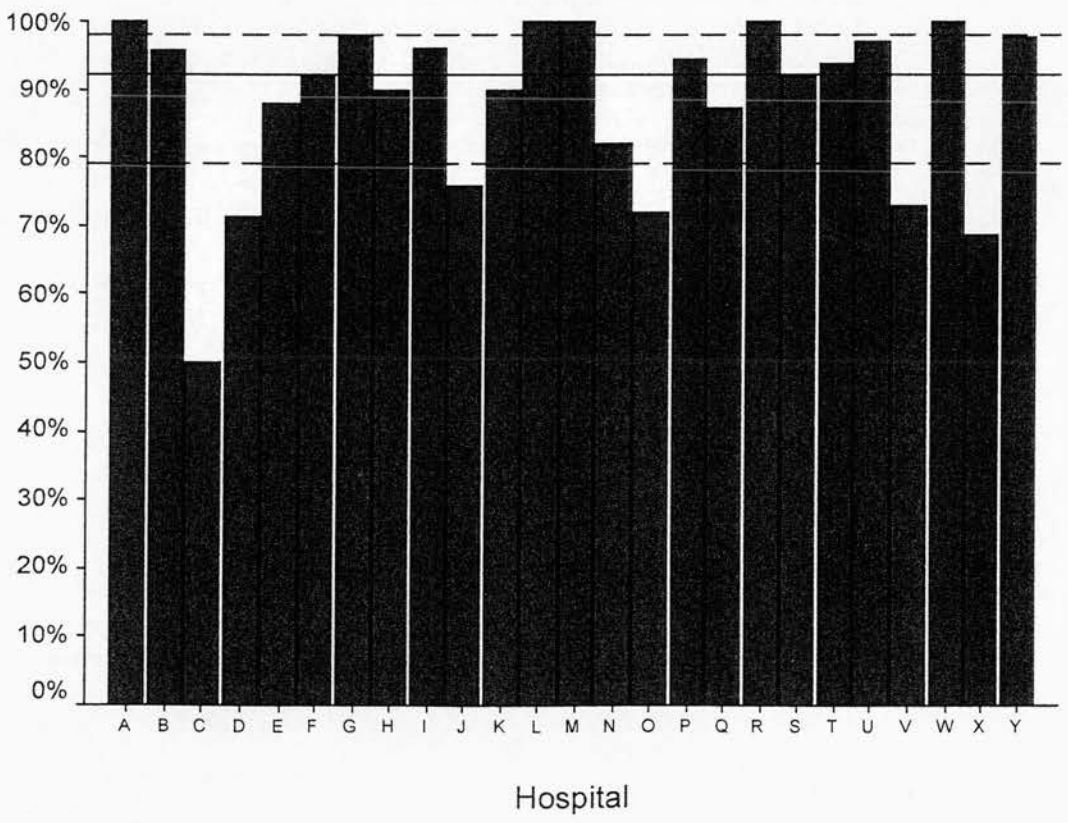


Figure 2. Percentage of women attending assessment appointment within 14 days of referral

Recommendation	Service arrangements should be such that: • Ideally, all women can undergo the abortion within seven days of the decision to proceed being agreed. • As a minimum standard, all women can undergo the abortion within two weeks of the decision to proceed being agreed. • As a minimum standard, no individual woman need wait longer than three weeks from her initial referral to the time of her abortion (Grade C)
Rationale	• The earlier in pregnancy an abortion is performed, the lower the risk of complications • Seven days as an appropriate target between assessment and procedure suggested by Birth Control Trust • Target also endorsed by a consensus survey of Scottish gynaecologists
Method of assessment	Proportion of patients with 7 or fewer days between date of assessment appointment and date of abortion, including administration of mifepristone (Figure 3) Proportion meeting minimum standard (i.e. within 14 days) calculated similarly (Figure 4). Proportion meeting minimum standard of not waiting longer than three weeks from initial referral to time of procedure (Figure 5). Data available for total of 1054 cases.
Comments	In relation to the interval between the assessment appointment and procedure, median compliance was 87% for the ideal target and 98% for meeting the minimum standard. No allowance was made for non-working days. Nor was it possible to assess when the actual decision to proceed with abortion was made. Hence, compliance with recommendation may be under-estimated for some cases. Ensuring that no woman needs to wait longer than 3 weeks between initial referral and the induced abortion procedure may represent the most important minimum standard. Units A, G, P and U met this standard for 100% of cases assessed. Units C and J had problems meeting this standard.

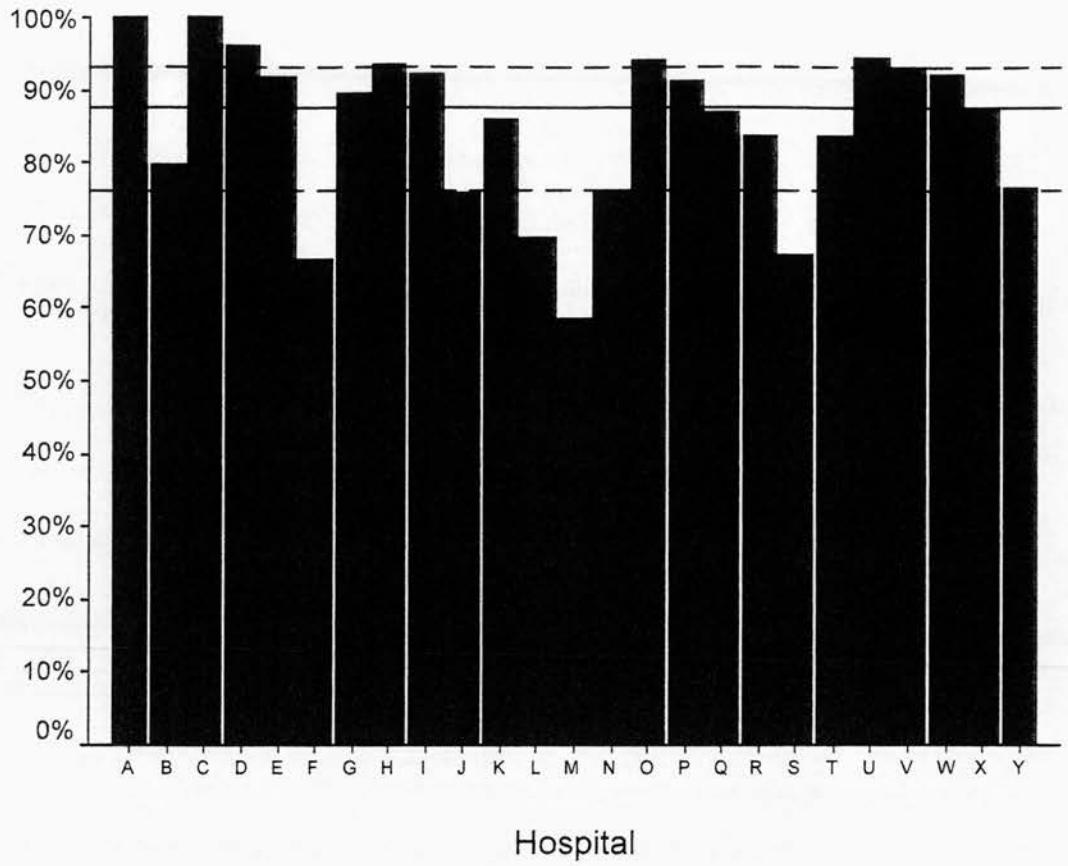


Figure 3. Percentage of induced abortions occurring within 7 days of clinic assessment

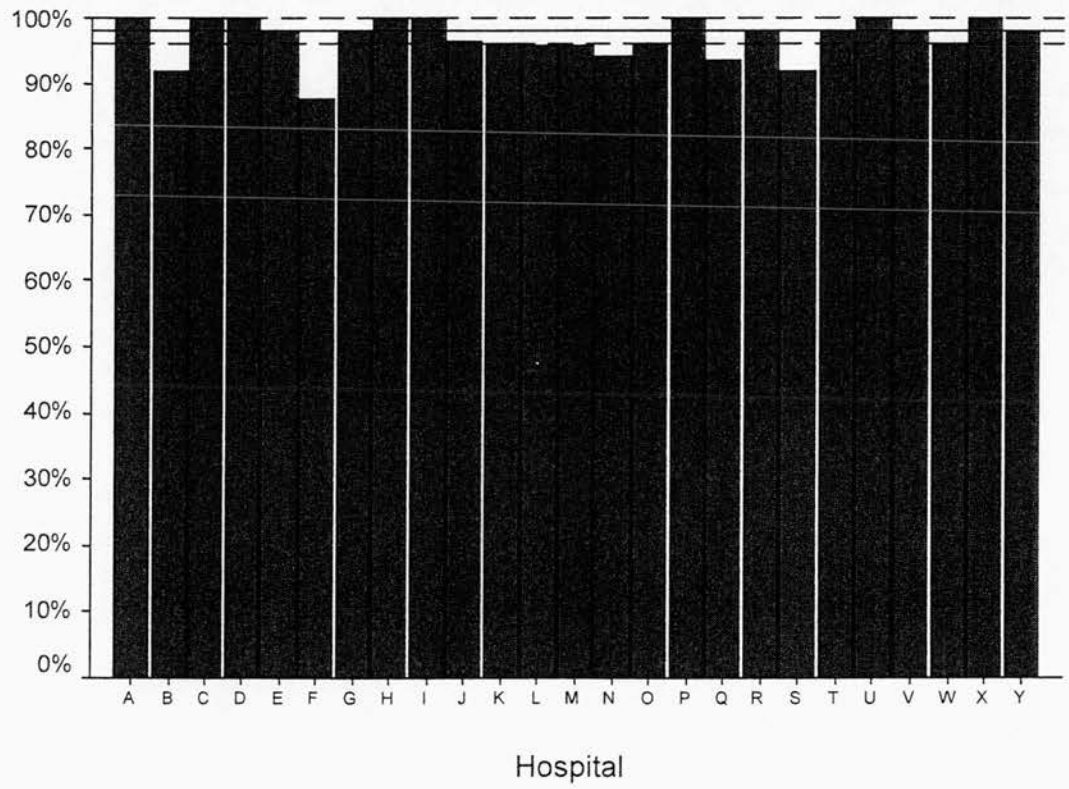


Figure 4. Percentage of induced abortions occurring within 14 days of clinic assessment

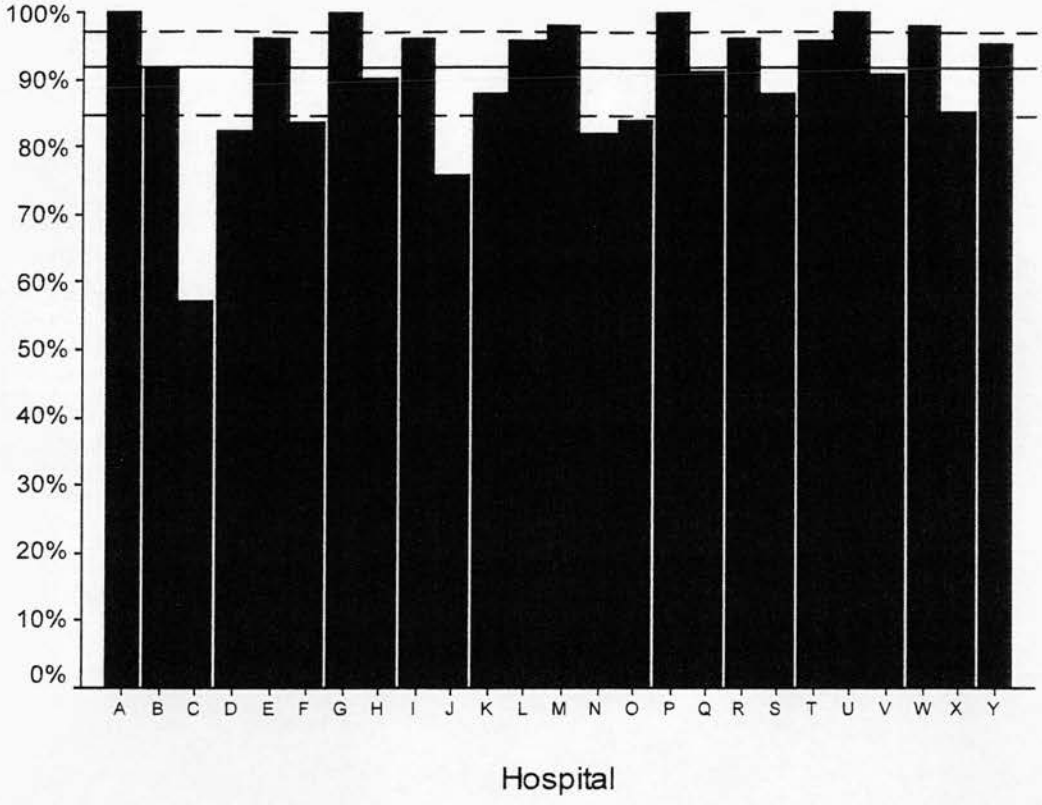


Figure 5. Percentage of induced abortions occurring within three weeks of initial referral.

Recommendation	In the absence of specific medical, social or geographical contra-indications, induced abortion may be managed on a day-case basis. (Good practice point)
Rationale	• Day care recognised as cost effective model of service provision • Minimisation of disruption to lives of women and their families • Need for inpatient care for some women, e.g. because of geographical factors, medical problems requiring assessment prior to anaesthetic or the lack of an adult companion at home
Method of assessment	Proportion of cases discharged on same day as admission, including day of administration of misoprostol for medical abortions (Figure 6). Data available for total of 1064 cases.
Comments	Median compliance was 96%. The four units (A, F, L and N) with lower proportions managed as day cases all serve rural or semi-rural populations.

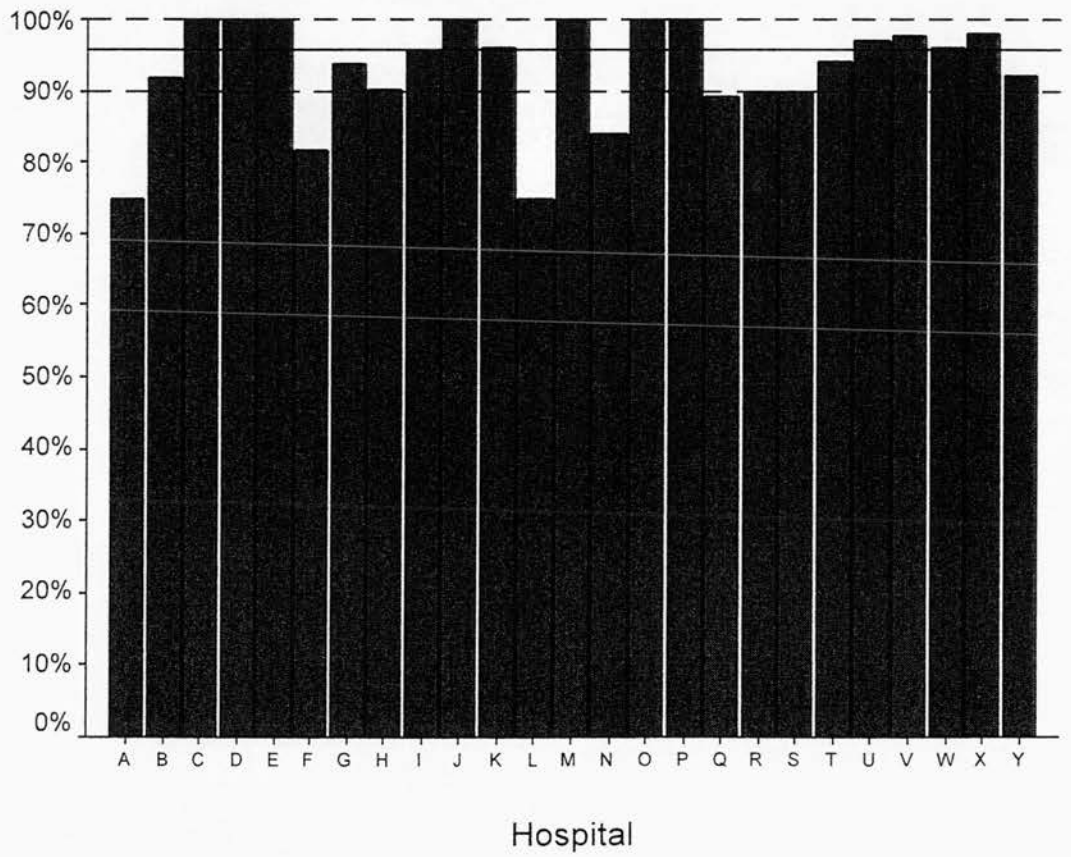


Figure 6. Percentage of induced abortions performed as day cases.

Pre-abortion management

Recommendation	Pre-abortion assessment should include: • Measurement of haemoglobin concentration • Determination of ABO and Rhesus blood groups with screening for red cell antibodies (Grade C)
Rationale	• Possibility of excessive blood loss associated with surgical abortion • Rhesus group ascertainment required for appropriate administration of Anti-D prophylaxis
Method of assessment	Proportion of patients having BOTH haemoglobin and blood group status checked (Figure 7). Data available for total of 1073 cases
Comments	Compliance with this standard was low in four units: A, E, G and P. In unit E, no women had any recorded measurement of haemoglobin.

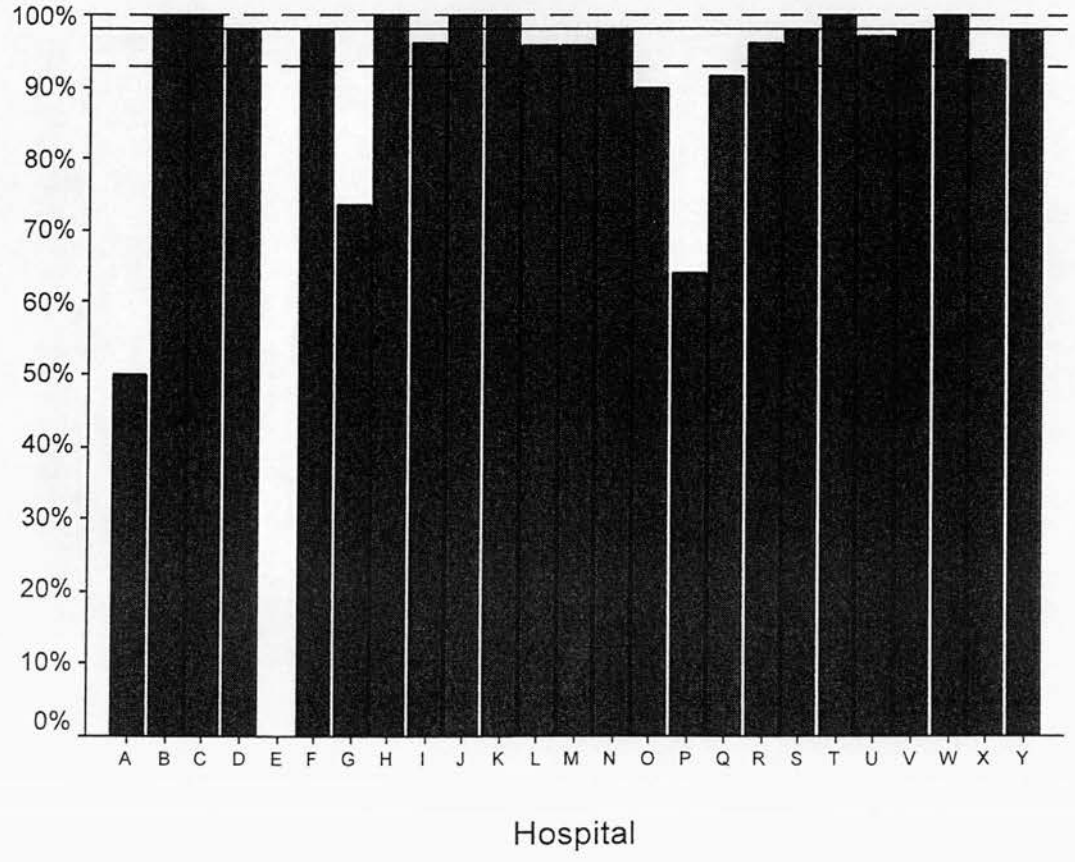


Figure 7. Percentage of women having appropriate blood tests.

Recommendation	It is not cost-effective routinely to cross-match women undergoing termination of pregnancy. (Grade B)
Rationale	• Rarity of requirement for blood transfusion following abortion • Proximity of blood banks on occasions when blood transfusion required
Method of assessment	Proportion of patients where cross matching was not performed (Figure 8). Data available for total of 1073 cases.
Comments	Most units met or were close to this standard, except for unit G. It is possible that for several cases, cross-matching was undertaken following complications with the abortion procedure. However, only 3 cases of high intra-operative blood loss and 2 case of actual or suspected uterine perforation occurred within the whole sample.

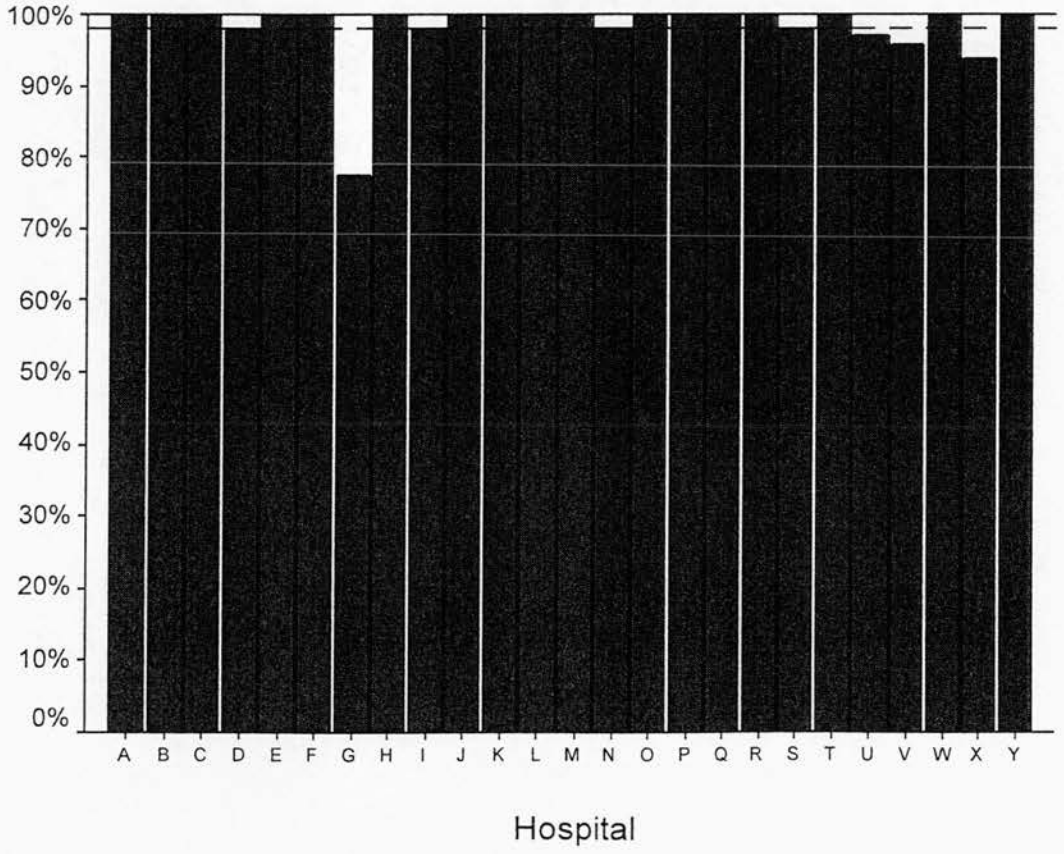


Figure 8. Percentage of women not cross-matched.

Recommendation	Assessment prior to induced abortion may be viewed as an opportunity to ascertain each woman's cervical cytology history. (Good practice point)
Rationale	Attendance for abortion care represents opportunity to review broader aspects of reproductive health care
Method of assessment	Proportion of patients 20 years or over with written evidence of smear enquiry in case notes (Figure 9). This may under-estimate true extent of ascertainment if enquiry made but not recorded Data available for total of 776 cases
Comments	There was marked variation between units. In four units (D, H, R and U) over 90% of women had cervical screening status recorded. In three units (B, C and K) less than 10% of women had their status recorded. Overall, there appears to be major scope for improvement in meeting this recommendation across in Scotland. Factors suggested that help meeting this recommendation: • High priority given to cervical screening • Fits in with routines, e.g. doing vaginal examinations in clinic • Expected norm • Structured case notes available Factors suggested that hinder meeting this recommendation: • Low priority of cervical screening in abortion care • Incompatible with local routines, e.g. do not do VEs at clinics • Little point in asking if unable or not planning smear at clinic • Less need for smears because of increased uptake of screening • Local advice against doing smears during pregnancy – even if due • Accidental omission, e.g. not on clerking sheet

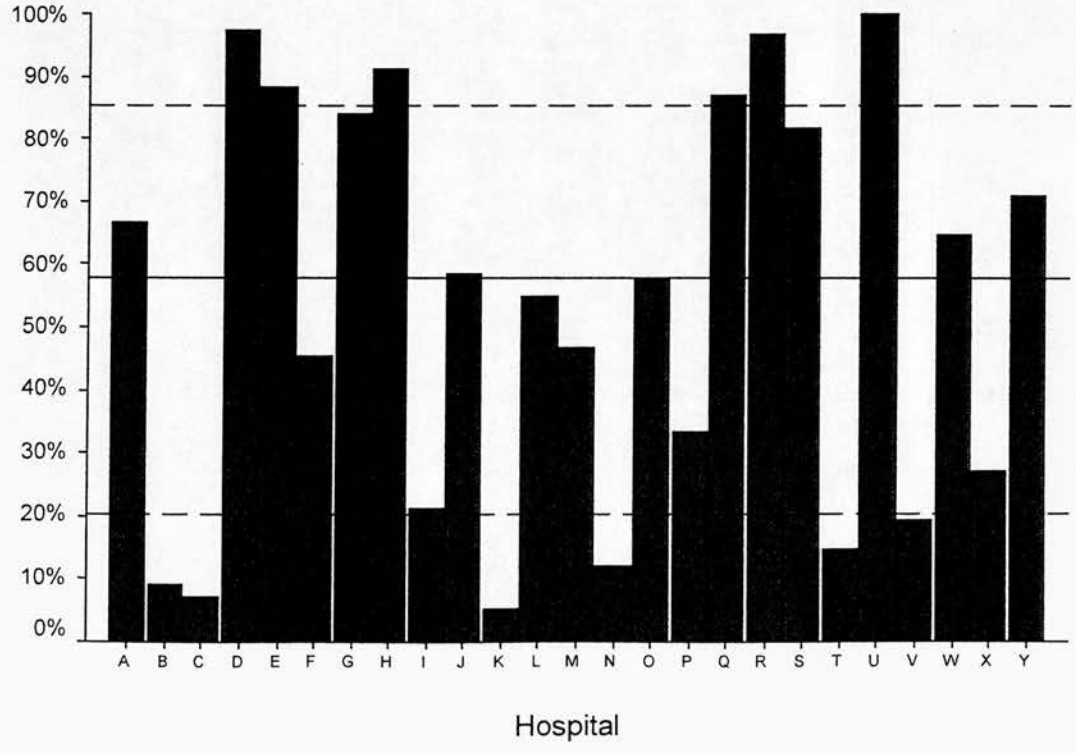


Figure 9. Percentage of women 20 years or over with record of enquiry into cervical smear status.

Recommendation	Women who have not had a smear within the interval recommended in their local programme may be offered a smear taken opportunistically. (Good practice point)
Rationale	As above
Method of assessment	Proportion of women 20 years or over with an enquiry into cervical cytology history who had • No smear taken within previous 3 years and had a smear taken at gynaecological assessment, and • Smear taken within previous 3 years and no smear taken at gynaecological assessment. (Figure 10) Data available for total of 413 cases.
Comments	Median compliance with this recommendation was 75% when a history of smear status was recorded. Compliance was less than 50% for units C, T and Y.

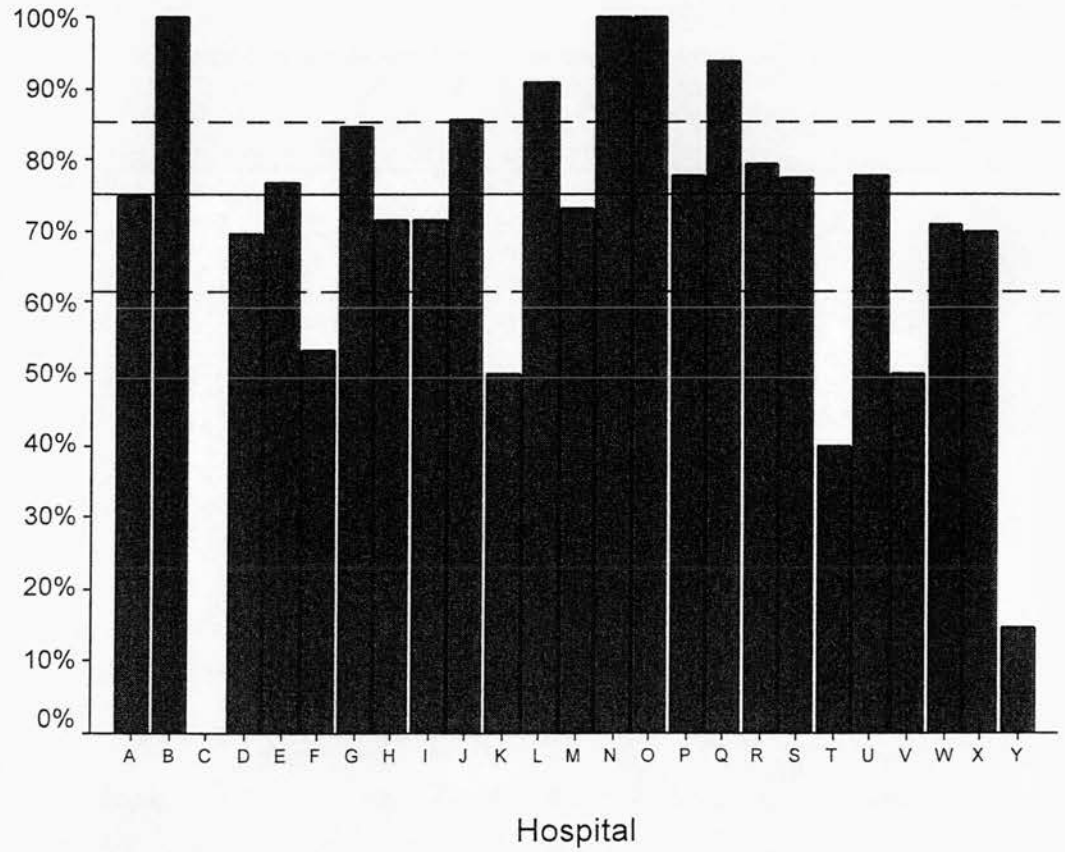


Figure 10. Percentage of patients with appropriate cervical smear history and action.

Recommendation	Ultrasound scanning is not considered to be an essential prerequisite of abortion in all cases. However, all units must have access to scanning as it can be a necessary part of pre-abortion assessment, particularly where gestation is in doubt or where extrauterine pregnancy is suspected. (Grade C)
Rationale	• Lack of randomised trials supporting ultrasonography in this context • Observational studies suggest use of ultrasonography alters estimated gestational age and subsequent methods of abortion in a minority of women
Method of assessment	Figure 11 shows the percentage of all women having scanning performed. Figure 12 shows the proportion of women either (a) not being scanned or (b) being scanned because the gestation was in doubt or extrauterine pregnancy was suspected. This does not account for women in whom scanning was indicated but not performed. It is also likely that the majority of ultrasounds were performed to check gestation but that this indication was not recorded Data available for total of 1073 cases.
Comments	The evidence supporting the routine use of ultrasound is arguably equivocal. However, accepting that many gynaecologists believe it has a valid role in pre-abortion assessment, scanning should be performed in an appropriate setting and manner which are sensitive to the woman's situation.

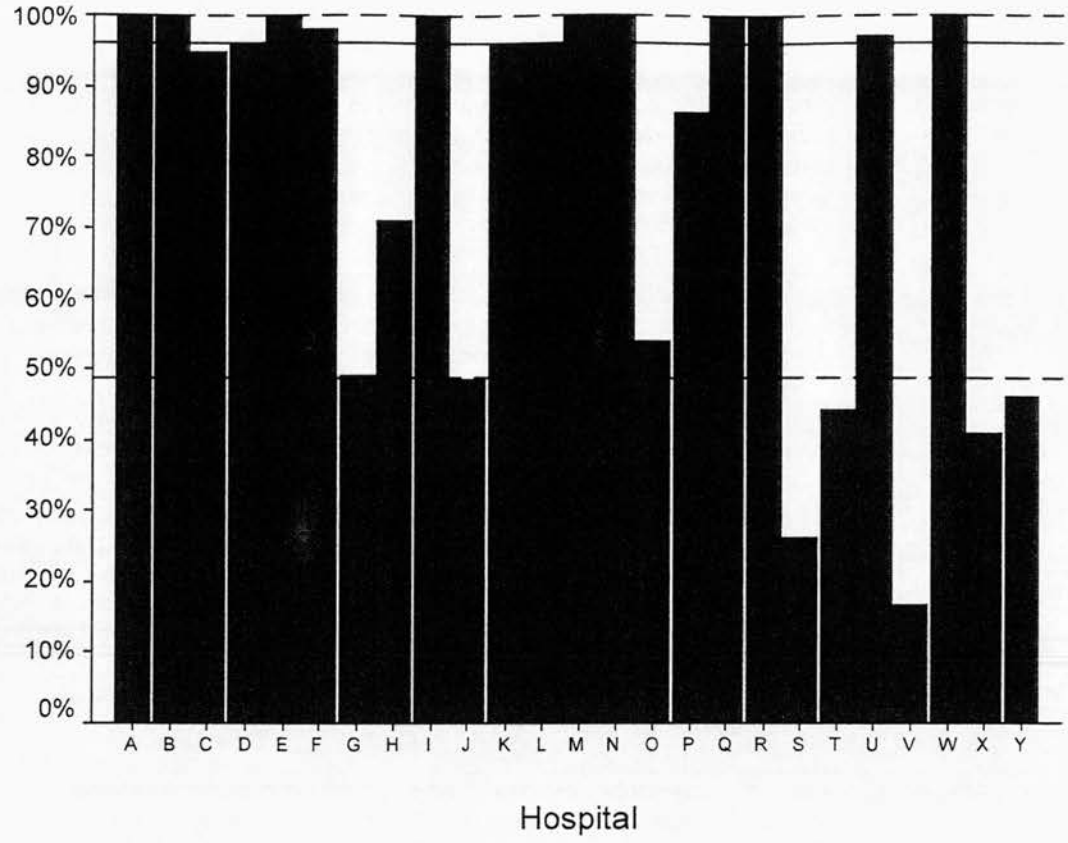


Figure 11. Percentage of women having ultrasonography performed.

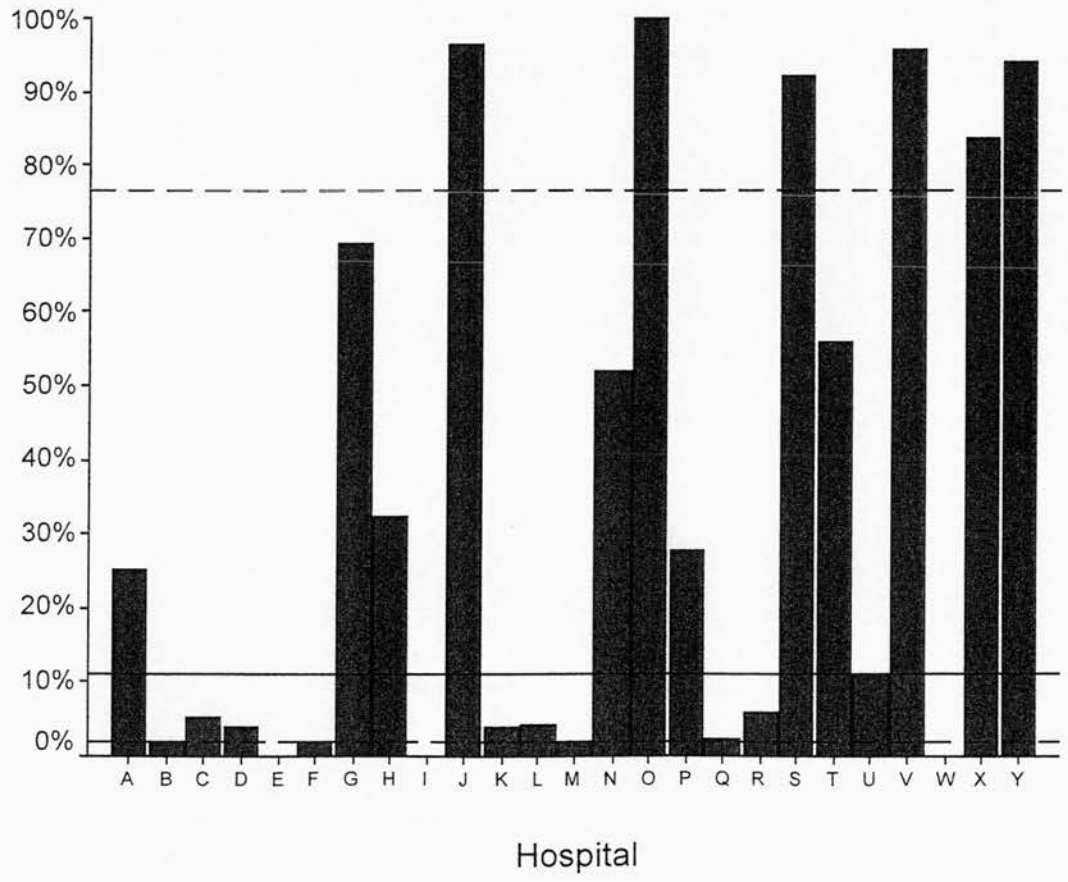


Figure 12. Percentage of women not having an ultrasound or having a recorded indication when ultrasound was performed.

Recommendation	Abortion care should encompass a strategy for minimising the risk of post abortion infective morbidity. Appropriate strategies include: • Antibiotic prophylaxis (Grade A), or • Screening for lower genital tract organisms with treatment of positive cases (Grade B).
Rationale	• Genital tract infection is recognised complication of abortion, possibly occurring in up to 10% of women not receiving antibiotic prophylaxis • Risk of long term sequelae: tubal infertility and ectopic pregnancy • Three main options exist: 1. Screening and treating positive cases 2. Universal antibiotic prophylaxis 3. Universal prophylaxis combined with screening • Universal antibiotic prophylaxis halves risk of infective morbidity and, by itself, is most cost-effective strategy for minimising short term infective sequelae of abortion • Universal prophylaxis with screening allows opportunity for contact tracing
Method of assessment	Proportion of women either (a) given antibiotic prophylaxis or (b) tested with documented treatment if positive (Figure 13). Data available for total of 1073 cases.
Comments	Compliance with this recommendation was generally high – and represents a substantial improvement since the 1992-3 national audit of abortion care (Gynaecology Audit Project in Scotland). The recommendation was not applied to any cases in unit C, and inconsistently applied in units X and Y. Factors suggested that help meeting this recommendation: • Convincing evidence base • Guideline produced by professional body (RCOG) – or covered by recent SIGN guideline • Prevalence of chlamydial infection • Unit guidance available • Expected local norm Factors suggested that hinder meeting this recommendation: • Negative attitudes, e.g. concern over acceptability to patients, some nursing staff consider speculum exam and swab taking unpleasant for patients

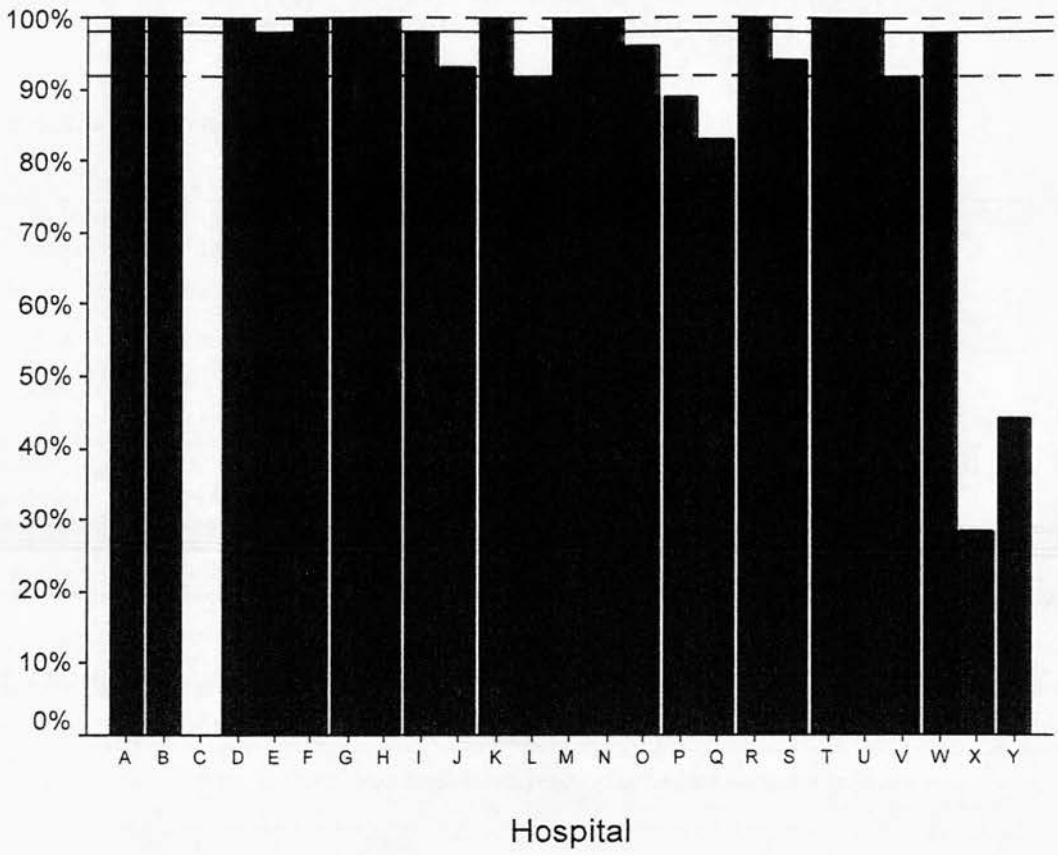


Figure 13. Percentage of women either given antibiotic prophylaxis or tested with documented treatment if positive.

Procedures

Recommendation	Medical abortion, using mifepristone plus prostaglandin, is an appropriate method at gestations of <7 weeks. (Grade B) Conventional suction termination should be avoided at gestations of <7 weeks. (Grade B)
Rationale	• Suction terminations performed at less than seven weeks gestation are three times more likely to fail to remove the gestation sac than those performed between 7-12 weeks. • For mifepristone / prostaglandin regimens used in early medical abortion the complete abortion rate falls as gestation advances • Medical abortion is at its most effective at earliest stages of pregnancy
Method of assessment	Proportion of women with gestation less than 7 weeks undergoing medical abortion (Figure 14). Data available for total of 132 cases. No relevant cases were available for units C, L and Y.
Comments	The bar chart requires cautious interpretation as it is based upon a relatively small number of cases per unit (range 1 to 18). However, units (B, E, I and W) with relatively higher numbers of women eligible for early medical abortion, between 10 and 20 cases each, generally performed better Compliance with this recommendation was 50% or less for six units (D, M, O, U, V and X). No relevant cases may have been identified in units C, L and Y because either no women were referred sufficiently early or this service is not available locally. Suction termination can be effective if conducted according to a rigorous published protocol. Compliance might therefore be underestimated if women categorised as having surgical abortions underwent procedures in accordance with such a protocol. It seems unlikely that this would apply to all cases and units performing relatively few early medical abortions may wish to review their current policies regarding access and provision.

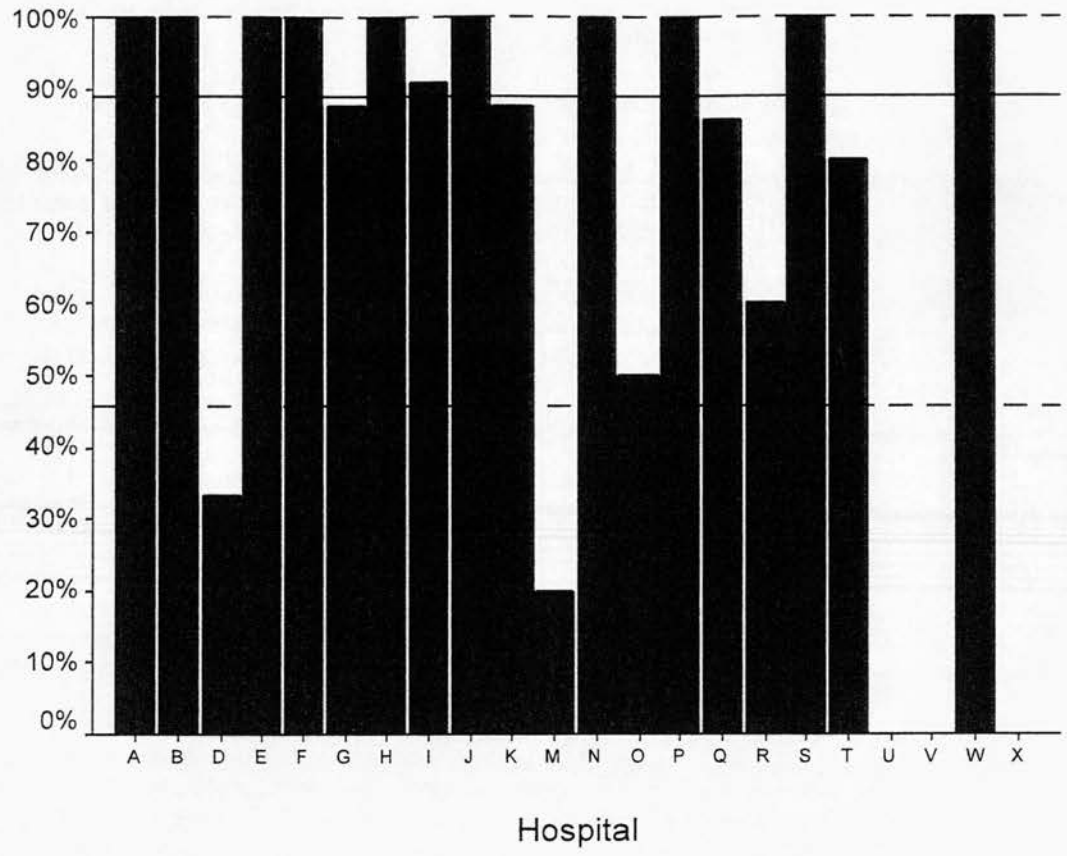


Figure 14. Percentage of women at less than 7 weeks gestation undergoing medical abortion.

Recommendation	For early medical abortion, a dose of 200mg of mifepristone, in combination with a prostaglandin is adequate. (Grade A)
Rationale	A dose of 200 mg mifepristone prior to prostaglandin administration for early medical abortion is as effective as the 600 mg dose (recommended in the manufacturer's data sheet)
Method of assessment	Proportion of women with pregnancies up to 9 weeks gestation undergoing early medical abortion prescribed 200 mg mifepristone (Figure 15). Data available for total of 354 cases. No relevant cases were available for units C, L, U, V and X.
Comments	All units providing medical abortion up to 9 weeks routinely used mifepristone 200 mg except unit Y.

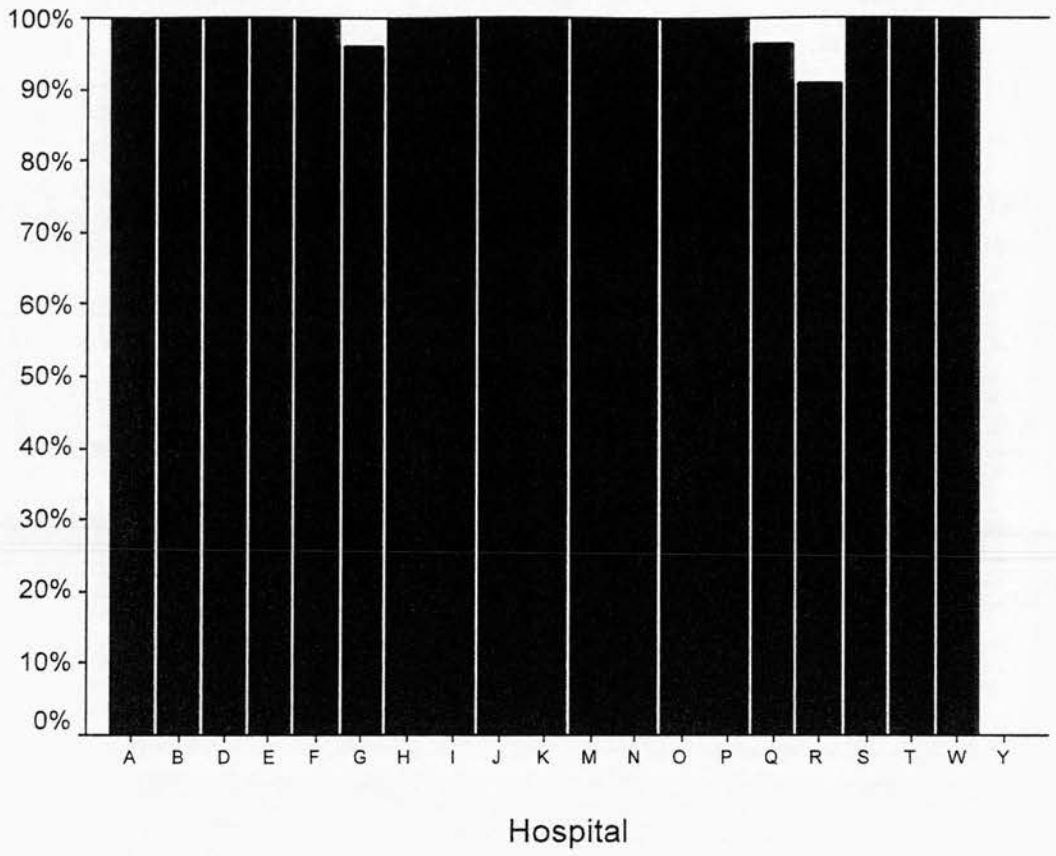


Figure 15. Percentage of women with pregnancies up to 9 weeks gestation undergoing early medical abortion prescribed 200 mg mifepristone.

Recommendation	Misoprostol (a prostaglandin E1 analogue), given vaginally is a cost-effective alternative for all abortion procedures for which the E1 analogue, gemeprost is conventionally used (early medical abortion, cervical priming, mid-trimester medical abortion). (Grade A)
Rationale	• Misoprostol less expensive and as effective as gemeprost at gestations of up to 7 weeks • At gestations of 7-9 weeks, the continuing pregnancy rate may be higher when misoprostol is used • Use of misoprostol by vaginal route constitutes an unlicensed indication and an unlicensed route of administration. However, the EC Pharmaceutical Directive 65/65/EEC specifically permits doctors to use 'licensed medicines for indications or in doses or by routes of administration outside the recommendations given in the license'. Patients should be properly informed before a drug is prescribed for an unlicensed indication. Drugs prescribed by doctors outside licence can be dispensed by pharmacists and administered by nurses and midwives.
Method of assessment	Proportion of women in whom misoprostol is used for early medical abortion, cervical priming and mid-trimester abortion (Figure 16). Data available for total of 1069 cases
Comments	Most units appeared to operate uniform policies of using either misoprostol or gemeprost. One unit (G) that used gemeprost at the time of data collection has now changed its policy. Other units (S, T, U and X) may wish to review their local policies. Factors suggested that help meeting this recommendation: • Convincing evidence base • Fewer side effects • Cost-effectiveness • Expected local norm • Routine part of care (e.g. written up at assessment clinic) Factors suggested that hinder meeting this recommendation: • Need further convincing of benefit • Not licensed / objections from colleagues or pharmacy • Greater familiarity with gemeprost • Delays caused by administration, e.g. unsuitable for cervical priming associated with 'fast track' abortion care

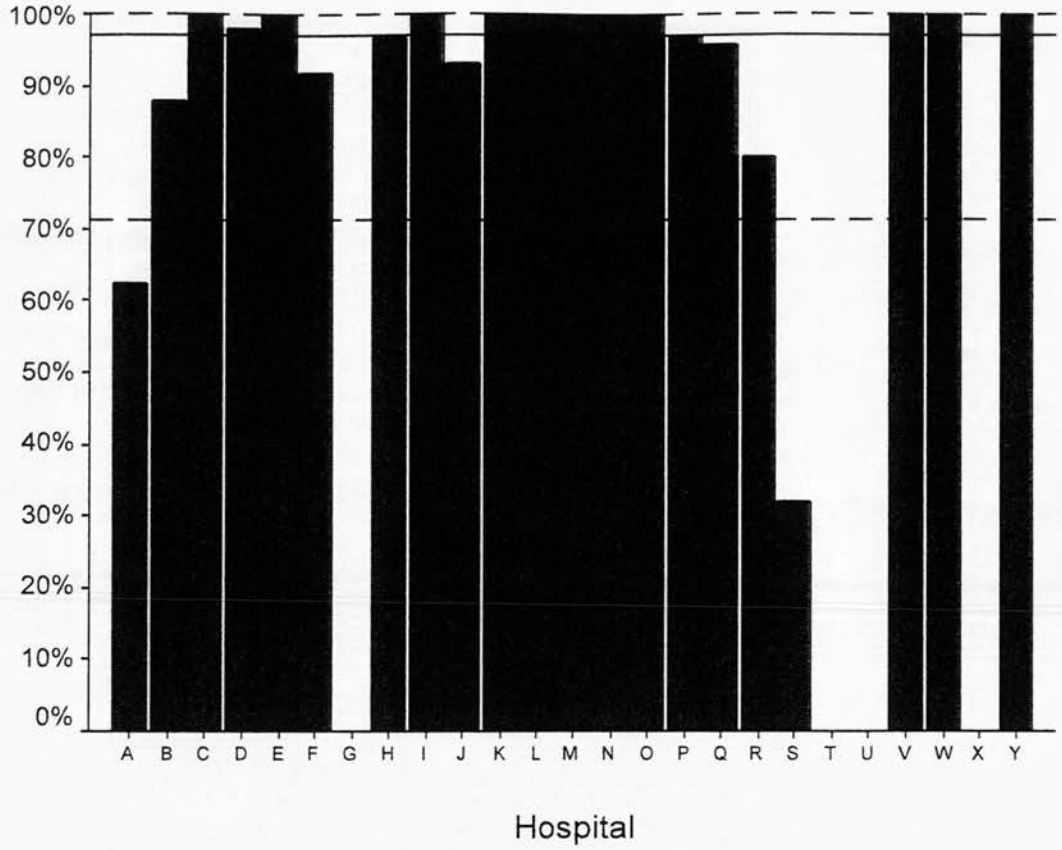


Figure 16. Percentage of women undergoing early medical abortion, cervical priming and mid-trimester abortion in whom misoprostol was used.

Recommendation	Use of conventional suction termination at gestations of 7-15 weeks if appropriate or preferred
Rationale	• Suction termination of pregnancy is currently the standard method at gestations of 9-12 weeks in the UK • Either suction termination or medical abortion are appropriate at gestations of 13 to 15 weeks
Method of assessment	Proportion of women at 7-15 weeks gestation inclusive undergoing surgical abortion (Figure 17). Data available for 918 cases.
Comments	There were wide variations in the proportions of women undergoing suction termination. This was the main or only method used in units C, L, O, U, V and X. These units may wish to review their ability to offer women medical as well as surgical terminations in the future.

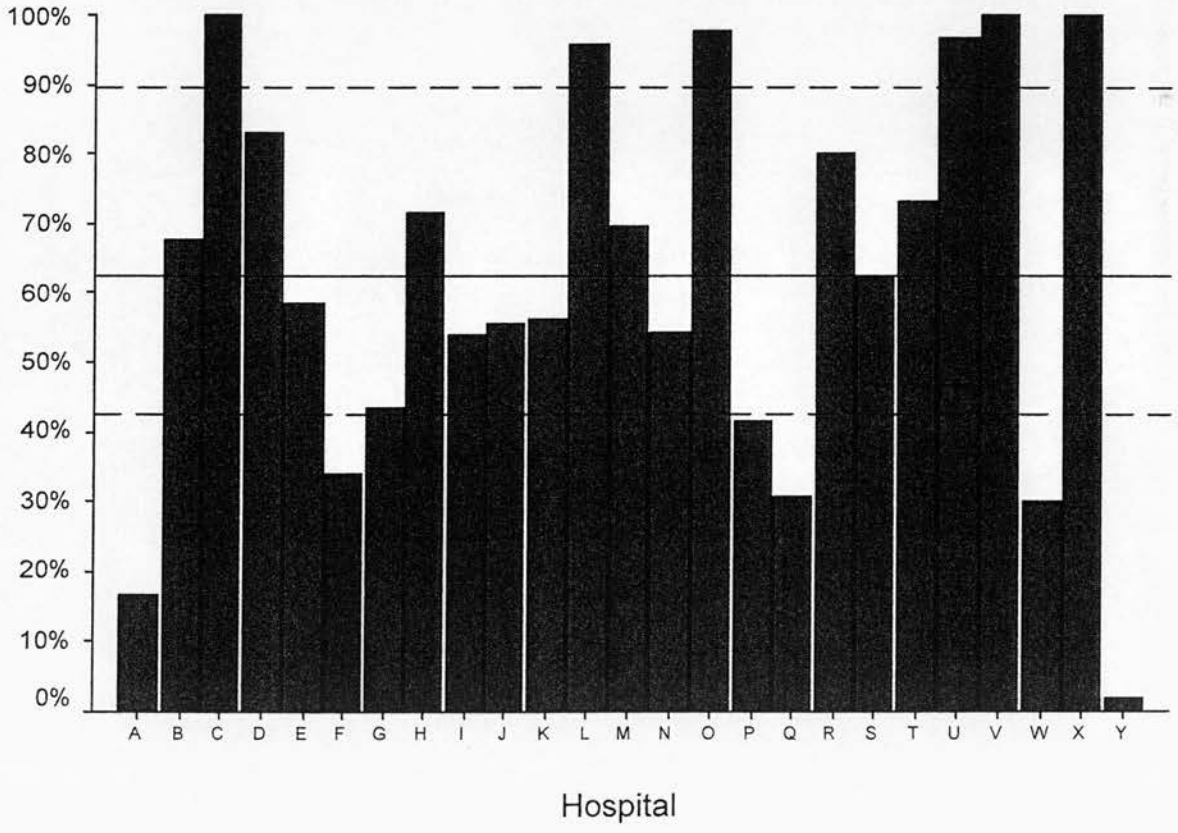


Figure 17. Percentage of women at 7-15 weeks gestation inclusive undergoing surgical abortion.

Recommendation	For women presenting between 7-15 weeks' gestation, suction termination may be safer under local anaesthesia than under general anaesthesia. Consideration should be given to making this option available. (Grade B)
Rationale	Lower complication rates and reduced time between admission and evacuation associated with local anaesthesia
Method of assessment	Proportion of women at 7-15 weeks gestation inclusive undergoing surgical abortion under local anaesthesia. Data available for total of 587 cases
Comments	No graph is provided as only 2 abortions were performed under local anaesthesia (one each in unit S and U). All units may wish to review the feasibility and acceptability of providing this option.

Recommendation	Cervical preparation is beneficial prior to suction termination and should be routine if the woman is aged under 18 years or at a gestation of >10 weeks. (Grade B)
Rationale	• Young patient age is a risk factor for cervical damage • Increasing gestation is associated with increasing risk of uterine perforation • Use of cervical priming reduces rates of both of these complications
Method of assessment	Proportion of all women undergoing surgical abortion receiving cervical priming (Figure 18). Data available for total of 604 cases Proportion of higher risk women (aged less than 18 years or over 10 weeks gestation) undergoing surgical abortion receiving cervical priming (Figure 19). Data available for total of 164 cases
Comments	Nearly all women in the higher risk category underwent cervical priming prior to surgical abortion, indicating a major improvement in practice since the Gynaecology Audit Project in Scotland took place.

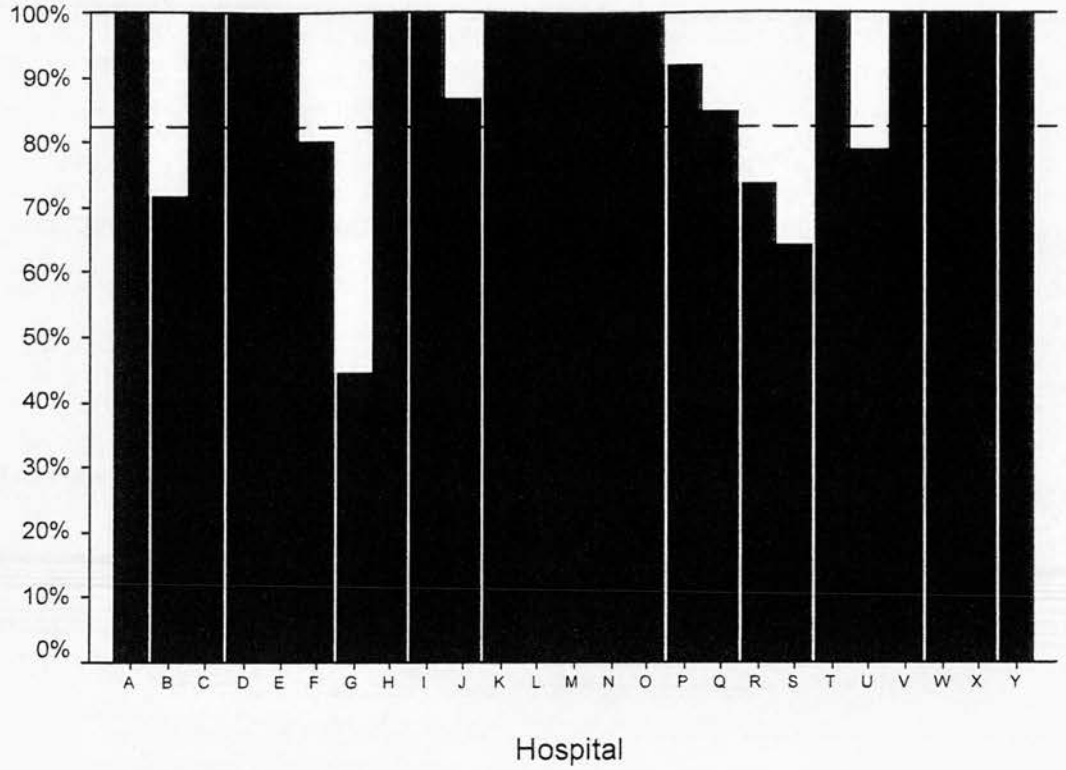


Figure 18. Percentage of all women undergoing surgical abortion receiving cervical priming.

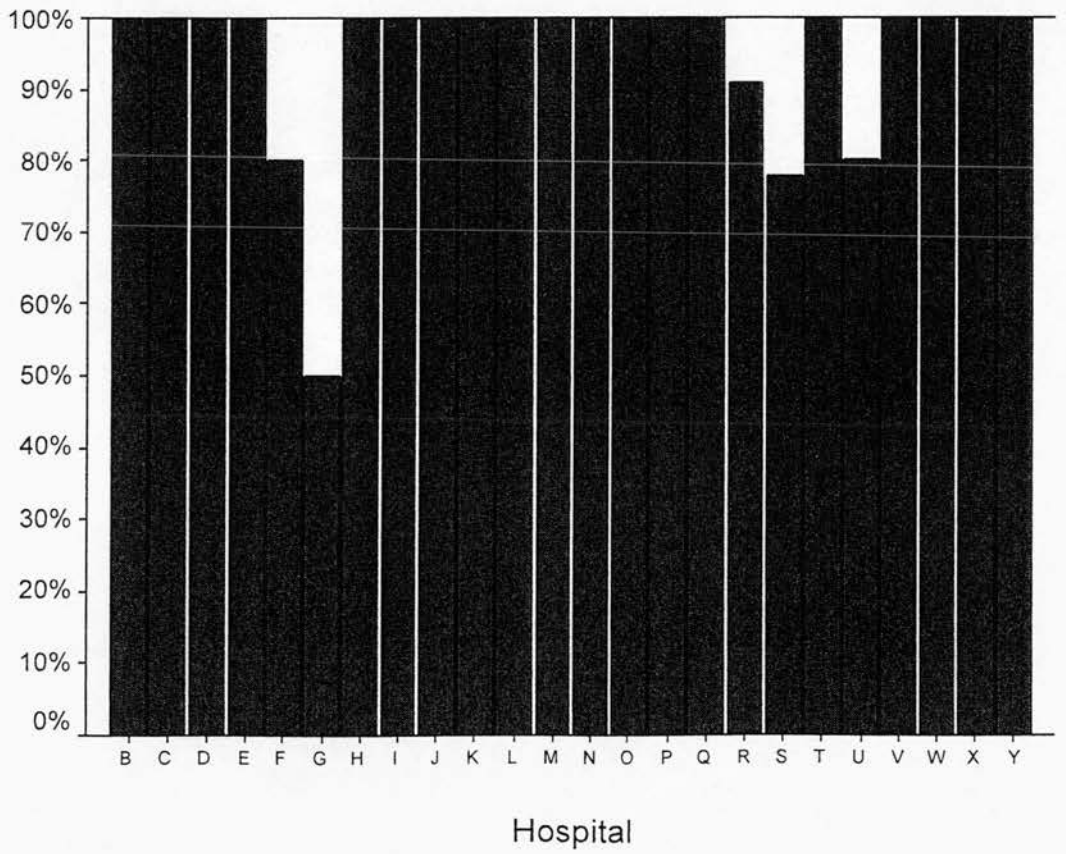


Figure 19. Percentage of higher risk women (aged less than 18 years or over 10 weeks gestation) undergoing surgical abortion receiving cervical priming.

Recommendation	For mid-trimester medical abortion, a dose of 200mg of mifepristone is adequate. (Grade A)
Rationale	Mifespristone at a dose of 200 mg is effective in second trimester abortions
Method of assessment	Proportion of women with pregnancies between 13 and 24 weeks (inclusive) gestation undergoing medical abortion prescribed 200 mg mifepristone. Data available for total of 65 cases. No relevant cases were available for units A, C, D, H, V and X.
Comments	Table 1 shows that there was 100% adherence to this recommendation where units provided this option.

Table 1. Number of women undergoing mid-trimester medical abortion prescribed 200 mg mifepristone.

Gynaecology unit	Number of women prescribed 200mg mifepristone	Number of eligible women
B	3	3
E	4	4
F	9	9
G	5	5
I	2	2
J	3	3
K	5	5
L	1	1
M	3	3
N	4	4
O	1	1
P	3	3
Q	4	4
R	1	1
S	6	6
T	2	2
U	2	2
W	4	4
Y	3	3
Total	65	65

Recommendation	Surgical evacuation of the uterus is not required routinely following mid-trimester medical abortion. It should only be undertaken if there is clinical evidence that the abortion is incomplete. (Grade B)
Rationale	Less than 10% of patients undergoing mid-trimester medical abortion subsequently require surgical evacuation
Method of assessment	Proportion of women having mid-trimester medical abortions (13 to 24 weeks inclusive) either (a) not undergoing surgical evacuation or (b) undergoing surgical evacuation indicated for incomplete abortion. Data available for total of 65 cases. No relevant cases were available for units A, C, D, H, V and X.
Comments	Table 2 shows an overall adherence of 95% to this recommendation.

Table 2. Number of women having mid-trimester medical abortions either (a) not undergoing surgical evacuation or (b) undergoing surgical evacuation indicated for incomplete abortion

Gynaecology unit	Number of women managed appropriately	Number of eligible women
B	3	3
E	4	4
F	8	9
G	5	5
I	1	2
J	3	3
K	5	5
L	1	1
M	3	3
N	4	4
O	1	1
P	3	3
Q	4	4
R	1	1
S	6	6
T	2	2
U	2	2
W	4	4
Y	2	3
Total	62	65

Recommendation	Mid-trimester abortion by dilatation & evacuation (D&E), preceded by cervical preparation, is safe and effective when undertaken by specialist practitioners with access to the necessary instruments and who have a sufficiently large case-load to maintain their skills. (Grade A)
Rationale	• Contemporary methods of mid-trimester medical abortion have not been compared with D&E • D&E is safer than older, instillation methods of mid-trimester medical abortion • Use of real time ultrasound scanning during D&E can further reduce the uterine perforation rate
Method of assessment	Proportion of women undergoing surgical abortion (greater than 15 weeks gestation) which is preceded by cervical priming and where a consultant or staff grade doctor is the most senior operator present. No cases were identified.
Comments	This procedure is not or seldom performed in Scotland.

Recommendation	For women presenting at greater than 15 weeks' gestation, as an alternative to D & E, services may prefer to offer medical abortion. (Grade B)
Rationale	For gynaecologists lacking the necessary expertise and case-load and their patients, mid-trimester medical abortion using mifepristone may be appropriate.
Method of assessment	Proportion of women with pregnancies greater than 15 weeks gestation undergoing medical abortion Data available for total of 30 cases. No relevant cases were available for units A, C, D, H, I, L, M, O, R, T, V and X.
Comments	Table 3 shows that there was 100% adherence to this recommendation.

Table 3. Number of women with pregnancies greater than 15 weeks gestation undergoing medical abortion.

Gynaecology unit	Number undergoing medical abortion	Number of eligible women
B	1	1
E	3	3
F	2	2
G	2	2
J	1	1
K	1	1
N	1	1
P	1	1
Q	1	1
S	5	5
U	2	2
W	2	2
Y	1	1
Total	23	23

Managing complications

Recommendation	Oxytocics are effective in reducing intra-operative blood loss (Good practice point)
Rationale	Significant in immediate blood loss shown by randomised trials assessing role of oxytocics during surgical abortion.
Method of assessment	Proportion of women undergoing surgical abortion with an estimated blood loss of over 500 ml who receive oxytocics. Data available for total of 3 cases.
Comments	This complication occurred in only 3 cases following surgical abortion. One case occurring in unit H did not receive oxytocics. One out of 2 cases occurring in unit J did not receive oxytocics.

Recommendation	In cases of suspected uterine perforation laparoscopy is the investigation of choice (Good practice point)
Rationale	• Case series indicate low rate of serious sequelae as a result of uterine perforation • Laparoscopy of use in deciding whether laparotomy is required
Method of assessment	Proportion of women with suspected uterine perforation undergoing laparoscopy. Data available for total of 2 cases
Comments	Both cases underwent laparoscopy: one in unit L; and 1 in unit S.

After care

Recommendation	Anti-D IgG should be given to all non-sensitised RhD negative women following abortion, whether by surgical or medical methods and regardless of gestational age. (Grade B)
Rationale	Prevention of RhD sensitisation
Method of assessment	Proportion of RhD negative women receiving anti-D (Figure 20). Data available for total of 194 cases
Comments	Across Scotland, a total of 12 out of 194 eligible women had no record of receiving anti-D prophylaxis. This may be related to poor documentation or accidental omission, possibly because of faster throughput. However, some units may wish to review discharge procedures. In particular, there was no record of prophylaxis for 2 out of 9 eligible women in unit X, and 3 out of 12 in unit Y.

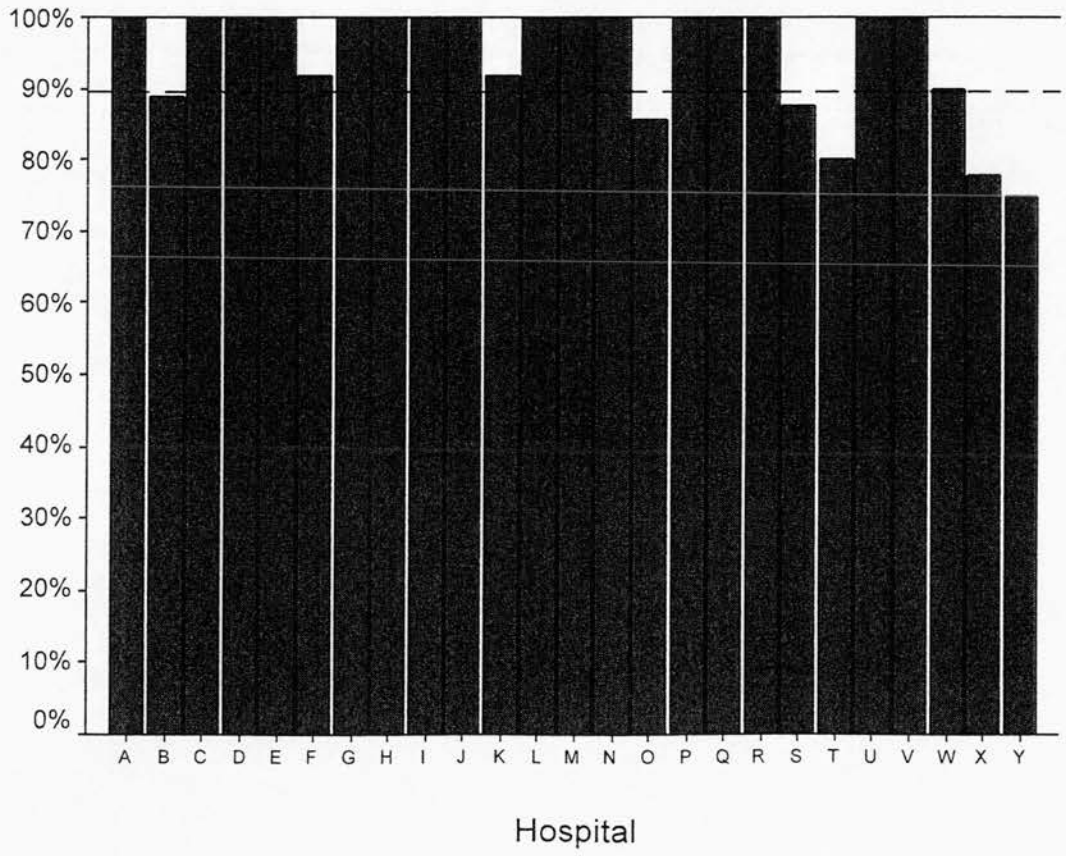


Figure 20. Percentage of RhD negative women receiving anti-D.

Recommendation	A follow-up appointment (either within the abortion service or with the referring clinician) within two weeks of the procedure should be offered to each patient following abortion. (Grade C)
Rationale	Follow up within two weeks required for early medical abortion (although optional if complete abortion is confirmed on day of procedure).
Method of assessment	Proportion of women with *any* documented follow-up appointment with abortion service or referring clinician (Figure 21). Figure 22 shows percentage of women with documented follow-up appointment within two weeks of discharge with abortion service or referring clinician. Data available for total of 1073 cases.
Comments	In 14 units, at least 75% of women had some documented offer of follow up, even if this only included advice to visit the referring doctor. Such an offer or advice was recorded much less frequently in units C, J and Y. Fewer units had any documented offer of follow up within 2 weeks. All women were offered follow up in unit O. Other units may wish to review their policies.

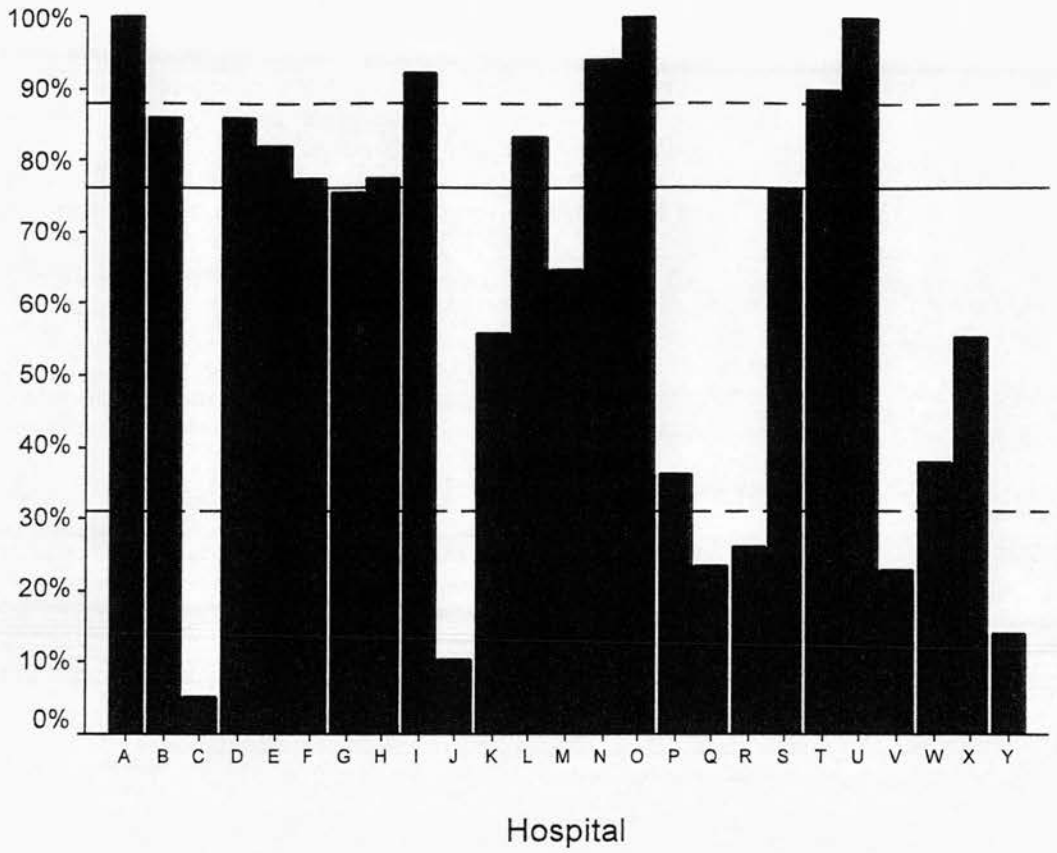


Figure 21. Percentage of women with any documented follow-up appointment with abortion service or referring clinician.

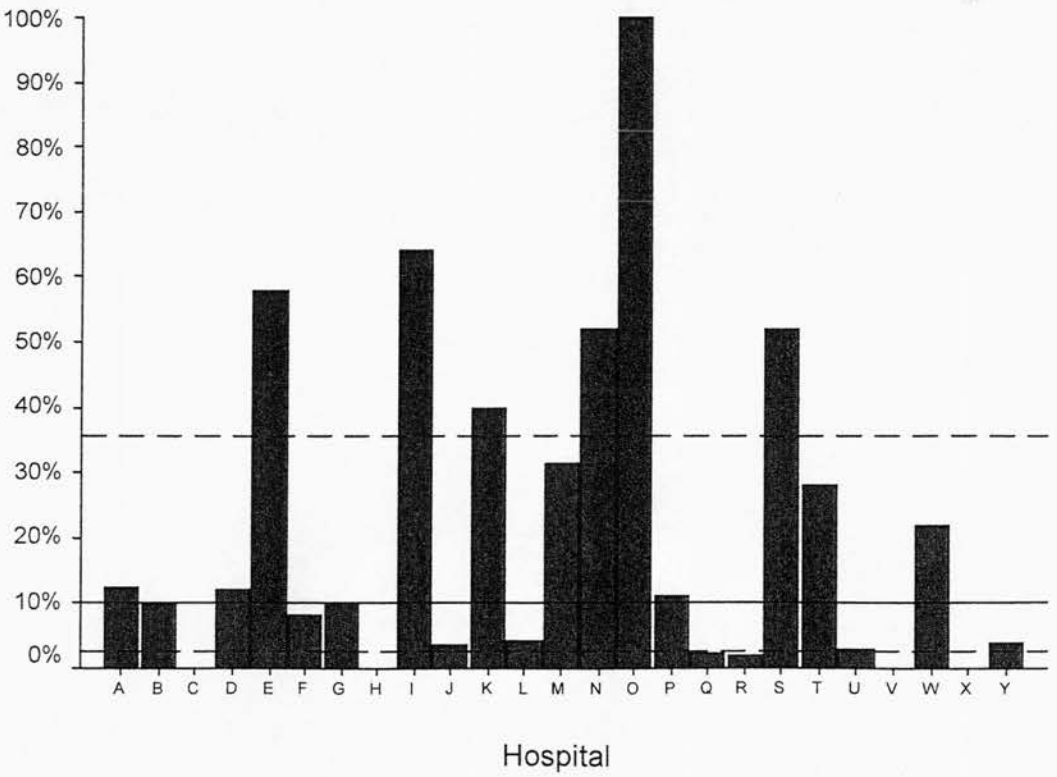


Figure 22. Percentage of women with documented follow-up appointment with abortion service or referring clinician made within two weeks of discharge.

Recommendation	Before she is discharged following abortion, future contraception should have been discussed with each patient and contraceptive supplies should have been offered if required. The chosen method of contraception should be initiated immediately following abortion. (Grade B)
Rationale	Ovulation occurs within a month of first trimester abortion in over 90% of women
Method of assessment	Proportion of women with documentation of discussion regarding future contraception (Figure 23). Proportion of women with documented supply of contraception from either referring clinician or gynaecology unit (Figure 24). Data available for total of 1073 cases.
Comments	The majority of women had some discussion of future contraception needs documented in most units. Documentation was poorer in units A, C, T and V. The assessment of provision of contraception at discharge underestimates compliance with the original recommendation, which concerned *offering* contraception. Less than half of women had documented provision in units A, C, F, P, T and X. It is also worth noting that this responsibility is often shared between primary and secondary care. However, units may wish to review procedures for checking whether the referring doctor has provided contraceptive supplies. Factors suggested that help the provision of contraceptive supplies: • High priority for gynaecologist and unit • Unit guidance available or reinforced within integrated care pathway form • Availability of family planning trained nursing staff • Availability of one or more methods Factors suggested that hinder the provision of contraceptive supplies: • Belief in 'patient choice' and responsibility during counselling • Uncertain impact on subsequent unwanted pregnancy rates • Provision is responsibility of others, e.g. GP / FPC responsibility • Lack of family planning trained nurses • Variable quality of family planning advice • Unavailability of choice of methods at discharge • Delays in obtaining supplies from pharmacy – or supplies not on ward

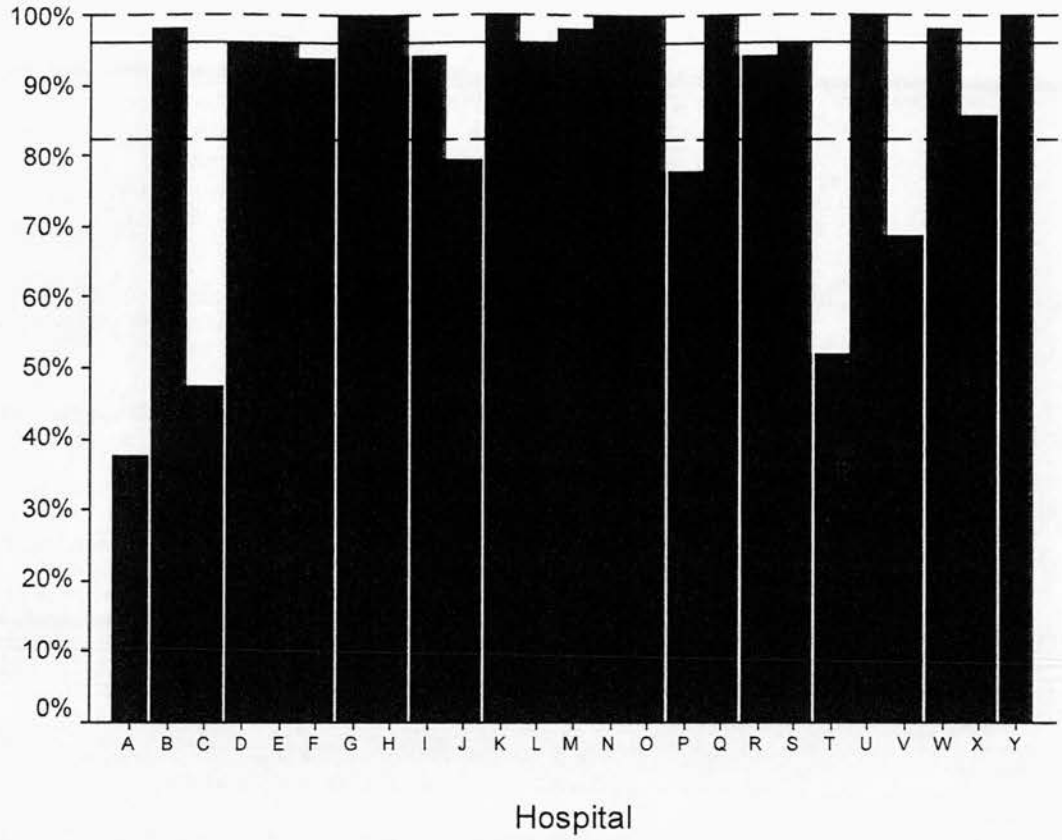


Figure 23. Percentage of women with documented discussion regarding future contraception.

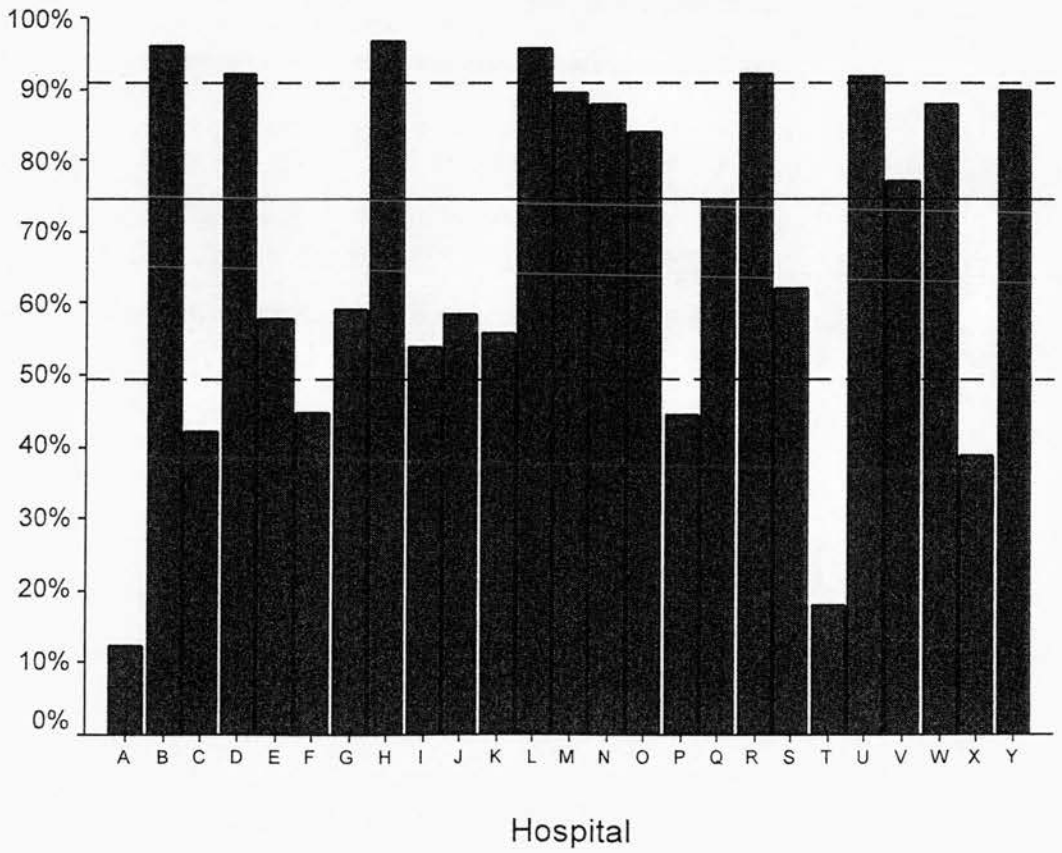


Figure 24. Percentage of women with documented supply of contraception from either referring clinician or gynaecology unit.

Recommendation	Sterilisation can safely be performed at the time of induced abortion. However combined procedures are associated with higher rates of failure and of regret on the part of the woman. (Grade B)
Rationale	• Comment by RCOG Medico-Legal Committee: 'In view of the increased failure rate of sterilisation procedures on those currently pregnant, it is questionable whether such operations should be carried out at all. Apart from the potential increased risk of failure, the possibility of feelings of regret has been voiced as a reason for performing sterilisation as an interval procedure.' • In one study, women requesting sterilisation at time of abortion were randomised to sterilisation in combination with abortion or an interval procedure; one third of those randomised to the interval procedure failed to attend.
Method of assessment	Proportion of women having abortions who underwent sterilisation at time of abortion procedure (Figure 25). Data available for 1073 cases. No relevant cases identified for unit A.
Comments	Only 16 women in total underwent sterilisation at the time of the abortion procedure. Ideally, this should be avoided. Anticipated difficulties with follow up following abortion (e.g. because of geographical factors) may explain this course of action for a number of cases..

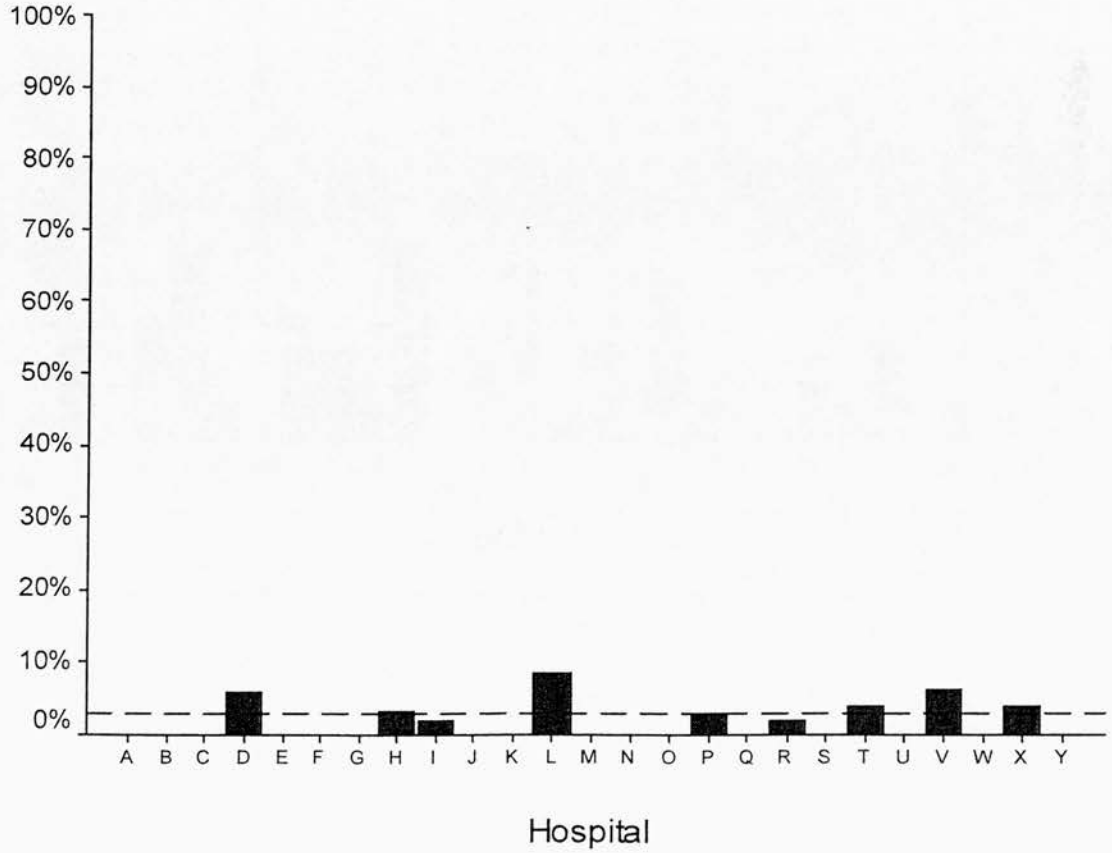


Figure 25. Percentage of all women undergoing abortion sterilised at time of abortion procedure.

Recommendation	It is safe and effective to insert an IUCD for contraceptive use immediately following induced abortion. (Grade A)
Rationale	Randomised studies demonstrating IUCD insertion following induced abortion is safe form of contraception, with no increase in post abortion infection rates and good toleration of devices
Method of assessment	Proportion of all women receiving contraception from hospital who had IUCD inserted at time of abortion procedure (Figure 26). Data available for 1073 cases.
Comments	The provision of IUCDs varies among units. Ideally, a range of contraceptive methods should be available immediately following contraception. Low proportions of usage in some units may be a chance finding or be related to unavailability.

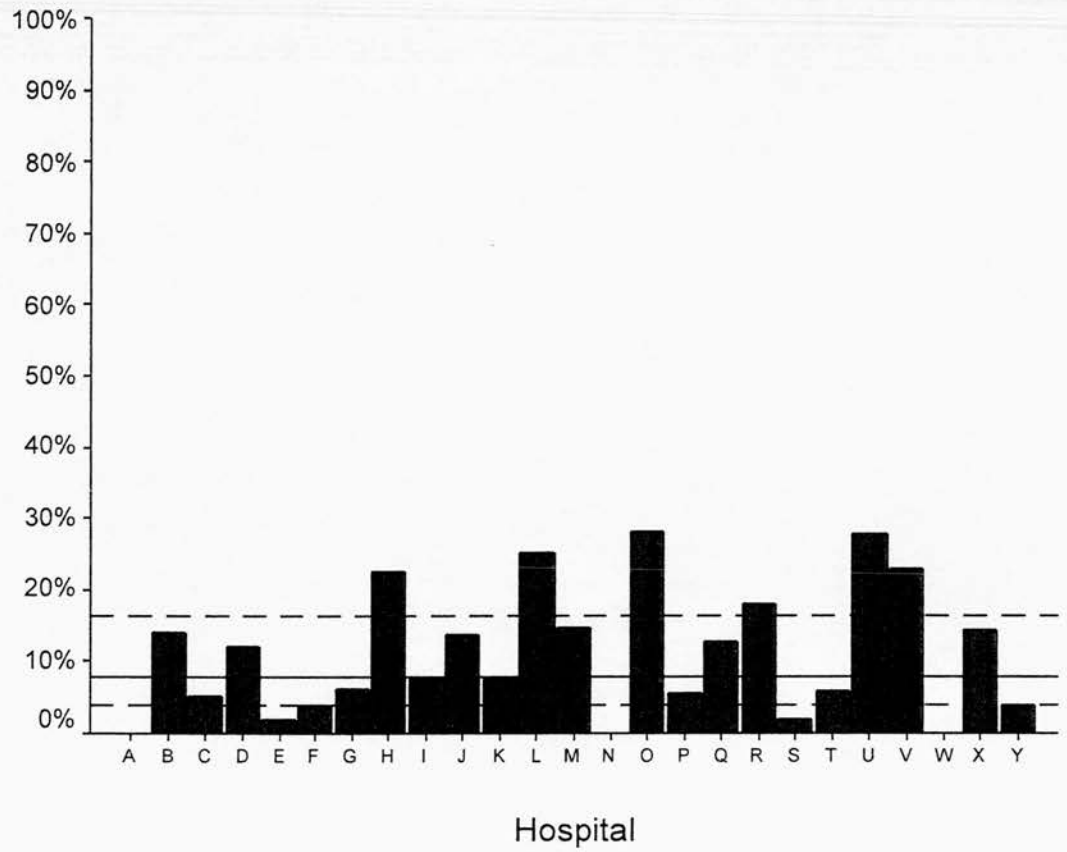


Figure 26. Percentage of all women receiving contraception from hospital who had IUCD inserted at time of abortion procedure.

Improving Abortion Care Trial (ImpACT)

ImpACT is a randomised trial to test the impact of additional support for the implementation of the guideline, *The Care of Women Requesting Induced Abortion*. All fellows and members of the RCOG have received identical printed guideline summaries. Half of the gynaecology units in Scotland have been randomised to the intervention group whilst the other half act as controls. The intervention 'package' comprises:

- Feedback of baseline audit data (including this document)
- An educational meeting
- A review of structured case records
- Promotion of a patient leaflet

The main outcome measure will be appropriateness of care, based upon adherence to with key recommendations from the clinical guideline. Adherence to the guideline recommendations will be assessed by a case note review and survey of women undergoing induced abortion. An economic analysis will also assess the efficiency of the intervention.

ImpACT is jointly run between the Scottish Programme for Clinical Effectiveness in Reproductive Health and the Health Service Research Unit (at Aberdeen University). In addition, gynaecologists from Glasgow, Edinburgh and Aberdeen are acting as clinical advisors to ImpACT.

The trial steering group members are:

Dr Robbie Foy (lead investigator)	MRC / CSO training fellow in health services research, Department of Reproductive and Developmental Sciences, University of Edinburgh
Dr Gillian Penney	National Coordinator, SPCERH, Dugald Baird Centre for Research in Women's Health, Aberdeen Maternity Hospital
Prof Jeremy Grimshaw	Programme Director, HSRU, University of Aberdeen
Dr Anna Glasier	Consultant / director, Family Planning and Well Women Services, Lothian Primary Care NHS Trust
Dr Alison Bigrigg	Consultant / director, Family Planning and Well Women Services, Greater Glasgow Primary Care NHS Trust
Prof Andrew Calder	Department of Reproductive and Developmental Sciences, University of Edinburgh (and Chairman of the RCOG Scottish Executive)
Dr Craig Ramsay	Senior statistician, HSRU, University of Aberdeen
Dr Anne Walker	Senior behavioural scientist, HSRU, University of Aberdeen
Dr Jim Chalmers	Consultant in public health medicine, Information and Statistics Division, NHS in Scotland
Dr Sally Stearns	Senior research fellow, Health Economics Research Unit, University of Aberdeen

The trial secretary is Ms Lorraine Adamson, based at the SPCERH office, Department of Reproductive and Developmental Sciences, University of Edinburgh.

IMPACT is funded by the Health Services Research Committee of the Chief Scientist's Office. The study has been approved by the multi-centre research ethics committee for Scotland and by all local research ethics committees.

Appendix 6D. Barriers identified from semi-structured interviews with lead gynaecologists

1	*Guideline recommendation*	*Mean baseline compliance*		*%*	
	Offer of appointment with a gynaecologist within five days of referral	*Help implementation (and number of units raising or discussing each point)*		*Hinder implementation (and number of units raising or discussing each point)*	
A	**Recommendation-specific factors**	Guideline produced by professional body (RCOG)	1	Lack of evidence supporting recommendation	
				Emailing or faxing of referrals hindered by need for accompanying green form	1
B	**Individual factors**	Women seeking abortion seen as high priority (usually by lead gynaecologist)	6	Women seeking abortion seen as low priority (usually by some or minority of clinicians)	5
		Flexibility of nursing staff, e.g. can do early medical abortions at weekends	1	Lack of feedback on waiting times	
				Doubt over potential benefits	
				Unfamiliarity with guideline or recommendation	
				Limited number of consultants perform abortions	2
				Junior doctors disagree with or reluctant to provide abortion care	3
C	**Organisational or environmental factors**	Existing telephone referral system	9	Delay mainly caused by referrer, e.g. postage of referrals	1
		Unit guidance or targets available	2	Insufficient resources to improve referral system / not organisational priority	3
		No limits on clinic appointments; or sufficient capacity	4	Coping with fluctuations in demand or supply (e.g. colleagues on leave, limited spaces on theatre lists)	9
		One secretary or person in charge coordinates appointments or clinic	5	No unit guidance or targets	
		Availability of day beds for 'fast-tracking'	1	Lack of facilities, e.g. clinic rooms, day or gynaecology beds, theatre capacity	6
		Reminders for GPs who refer by letter	2	Lack of medical staffing for clinic	2
		Staff available to provide care, e.g. nurses	1	External threats, e.g. risk of reduced capacity if move to surgical day care, under pressure to drop protected spaces for STOPs from lists	2
		All GPs and FPCs circulated	1	Limit numbers to allow for adequate counselling	2
		Dedicated clinic or list	2	Delays caused by out-of-district or other routes of referrals to consultants	1
		Accept faxed letters	1		

2	*Guideline recommendation*	*Mean baseline compliance*		*%*	
	Ascertainment of cervical cytology history	*Help implementation (and number of units raising or discussing each point)*		*Hinder implementation (and number of units raising or discussing each point)*	
A	**Recommendation-specific factors**	High priority given to cervical screening	2	Low priority of cervical screening in abortion care	1
		Guideline produced by professional body (RCOG)		Little point in asking if unable or not planning smear at clinic	1
		Fits in with routines, e.g. doing vaginal examinations anyway in clinic	2	Incompatible with local routines, e.g. do not do VEs at clinics	1
				Many patients under 20 years and ineligible for screening	3
				Local consensus / guidance / advice against doing smears during pregnancy – even if due; GP task	3
				Low outcome expectancy, i.e. less need for smears because of increased uptake of screening	2
B	**Individual factors**			Accidental omission, e.g. not on clerking sheet	4
				Low outcome expectancy	
				Low recording?	4
				Omissions more likely if delegated to junior staff	1
				Workload at clinic	2
C	**Organisational or environmental factors**	Expected norm	4	Not expected norm	2
		Unit guidance available	1	No unit guidance	
		Structured case notes available	3	Insufficient time	
		Structured post-abortion letter mention need for smears	1	Women don't expect smear at clinic	1
				Staff become responsible for dealing with subsequent results, e.g. should leave to GPs	1

3	*Guideline recommendation*	*Mean baseline compliance*		*%*	
	Antibiotic prophylaxis or screening for lower genital tract organisms	*Help implementation (and number of units raising or discussing each point)*		*Hinder implementation (and number of units raising or discussing each point)*	
A	**Recommendation-specific factors**	Convincing evidence base	3	Uncertainty over supporting evidence	
		Reduction of complications	2	Lack of local consensus	1
		Guideline produced by professional body (RCOG) – or covered by recent SIGN guideline	3		
		Easy to do	1		
		Prevalence of chlamydial infection	2		
B	**Individual factors**			Low outcome expectancy (perceived because infection is uncommon or high number needed to treat)	
				(Some) patients not perceived as high risk	
				Accidental omission	
				Negative attitudes, e.g. concern over acceptability to patients, some nursing staff consider speculum exam and swab taking unpleasant for patients	2
C	**Organisational or environmental factors**	Unit guidance available	7	No unit guidance	
		Expected local norm	10	Not expected norm	
				Disruption to routine practice	2
				Pharmacy concerns about budgetary impact	1

4	*Guideline recommendation*	*Mean baseline compliance*		*%*	
	Misoprostol cost-effective alternative to gemeprost (in early medical abortion, cervical priming and mid-trimester medical abortion)	*Help implementation (and number of units raising or discussing each point)*		*Hinder implementation (and number of units raising or discussing each point)*	
A	**Recommendation-specific factors**	Convincing evidence base	4	Uncertainty over evidence base	
		Guideline produced by professional body (RCOG)	3	Not licensed / objections from colleagues or pharmacy	4
		Fewer side effects	3	Need further convincing of benefit, e.g. by conduct of local audit	1
		Ease of storage	2		
		Familiarity with misoprostol	1		
B	**Individual factors**	Cost-effectiveness seen as priority	10	Individual clinical autonomy (and antipathy to cost-containment)	
				Greater familiarity with gemeprost	2
C	**Organisational or environmental factors**	Unit guidance available	3	No unit guidance	
		Expected local norm	5	Not expected local norm	
		Routine part of care (e.g. written up at assessment clinic)	2	Delays caused by administration, e.g. unsuitable for cervical priming associated with 'fast track' abortion care	1
		Pressure from finance department	1		

5	*Guideline recommendation*	*Mean baseline compliance*			*%*
	Offer of contraceptive supplies if required	*Help implementation (and number of units raising or discussing each point)*		*Hinder implementation (and number of units raising or discussing each point)*	
A	**Recommendation-specific factors**	Convincing evidence		Belief in 'patient choice' and responsibility during counselling	1
		Guideline produced by professional body (RCOG)	1		
		Concern regarding quality of follow up by GPs	1		
B	**Individual factors**	High priority for gynaecologist	7	Low outcome expectancy – uncertain impact on subsequent outcomes	1
				Accidental omission	1
				Low priority for gynaecologist, e.g. versus GP / FPC responsibility	1
				Low or inconsistent recording (or ascertainment during IMPACT data collection)	3
C	**Organisational or environmental factors**	Availability of one or more methods	7	Unavailability of choice of methods at discharge, e.g. Mirena	4
		High priority for unit	4	Delays in obtaining supplies from pharmacy – or supplies not on ward	2
		Unit guidance available	5	Low priority for unit	
		Covered in local staff training	2	Lack of shared protocol or communication with referrer	
		Availability of FP trained nursing staff	4	No unit guidance	1
		No pharmacy delays; pharmacy and day surgery next to one another	2	Need for FP trained nurses	2
		Repeated on integrated care pathway form	1	Variable quality of FP advice	1
				Patients discharged prior to returning for mirena or implanon	1

Appendix 6E. Interim analysis of staff survey

Table E1. Response rates to staff survey by discipline and grade (preliminary analysis).

Grade of recipient	*Number of recipients*	*Number completing questionnaires**	*Response rate (%)*
Consultants	43	33	**77**
Staff Grades	5	4	**80**
Specialist Registrars	31	17	**55**
SHOs	45	16	**36**
Nursing and midwifery sisters	23	15	**65**
Staff midwives and nurses	58	27	**46**
Total	**205**	**112**	**55**

*Excludes four responses where grade unknown

Table E2. Response rates to staff survey by gynaecology unit (preliminary analysis).

Gynaecology unit	*Number of recipients*	*Number completing questionnaires**	*Response rate (%)*
A	6	5	**69**
B	18	11	**61**
C	-	-	
D	15	9	**60**
E	8	8	**100**
F	31	16	**51**
G	22	12	**54**
H	14	10	**71**
I	14	9	**64**
J	18	10	**56**
K	23	10	**43**
L	8	4	**50**
M	28	10	**36**
Total	**205**	**114**	**56**

*Excludes two responses where unit unknown

Table E3. Pre-intervention compliance with assessment appointment within 5 days of referral (preliminary analysis).

Compliance	*Units*	*Respondents*
Lower (< 19.5%)	3	18
Moderate (19.5 – 46%)	7	64
Higher (>46%)	3	28

Table E4. Pre-intervention compliance with offer of contraceptive supplies at discharge (preliminary analysis).

Compliance	*Units*	*Respondents*
Lower (< 49%)	3	20
Moderate (49-94%)	7	66
Higher (>94%)	3	25

Table E5. Raw data on assessment of appointment within 5 days of referral (preliminary analysis).

	Reliability	*Mean*	*SD*	*Median*	*Minimum*	*Maximum*
Behavioural intention	0.89	6.14	1.19	6.67	1.00	7.00
Attitude	0.81	6.41	0.97	7.00	2.50	7.00
Subjective norm	0.43	5.83	0.97	6.00	3.00	7.00
Perceived control	0.80	3.94	1.37	4.00	1.00	7.00

Table E6. Raw data on offer of contraceptive supplies at discharge (preliminary analysis).

	Reliability	*Mean*	*SD*	*Median*	*Minimum*	*Maximum*
Behavioural intention	0.95	6.69	0.90	7.00	2.00	7.00
Attitude	0.84	6.76	0.78	7.00	2.50	7.00
Subjective norm	0.59	6.48	0.69	6.67	3.33	7.00
Perceived control	0.82	6.09	1.17	6.60	1.00	7.00

Table E7. Scores on psychological measures [mean (SD)] according to pre-intervention compliance for assessment appointment within 5 days of referral (preliminary analysis).

	Pre-intervention compliance			F	p
	Low	*Medium*	*High*		
Behavioural intention	5.78 (1.31)	6.18 (1.19)	6.25 (1.13)	0.96	0.38
Attitude	6.82 (0.47)	6.27 (1.02)	6.43 (1.06)	2.28	0.11
Subjective norm	5.76 (0.89)	5.75 (0.94)	6.01 (1.09)	0.69	0.50
Perceived control	2.82 (1.50)	3.87 (1.30)	4.77 (0.95)	12.31	<0.001

Table E8. Scores on psychological measures [mean (SD)] according to pre-intervention compliance for offer of contraceptive supplies at discharge (preliminary analysis).

	Pre-intervention compliance			F	p
	Low	*Medium*	*High*		
Behavioural intention	6.5 (1.16)	6.70 (0.79)	6.76 (1.01)	0.51	0.60
Attitude	6.61 (0.63)	6.81 (0.72)	6.70 (1.06)	0.59	0.56
Subjective norm	6.12 (0.84)	6.53 (0.56)	6.58 (0.81)	3.38	0.04
Perceived control	5.43 (1.15)	6.12 (1.25)	6.49 (0.73)	4.97	0.009

Table E9. Correlations (Pearson's r) between psychological measures for assessment appointment within 5 days of referral (preliminary analysis).

	Behavioural intention	*Attitude*	*Social pressure*
Behavioural intention	-		
Attitude	0.32**	-	
Subjective norm	0.52**	0.46**	-
Perceived control	0.26**	0.13	0.24**

**Correlation significant at the 0.01 level (2-tailed).

Table E10. Linear regression of behavioural intentions onto psychological measures adjusting for the clustering in the data for assessment appointment within 5 days of referral (preliminary analysis).

	Regression coefficient (B)	*Standardised regression coefficient (Beta)*	*95% CI*	*p*
Attitude	0.13	0.10	- 0.11, 0.37	0.26
Subjective norm	0.54	0.43	0.30, 0.77	<0.001
Perceived control	0.12	0.14	-0.03, 0.27	0.11

Table E11. Correlations (Pearson's r) between psychological measures for offer of contraceptive supplies at discharge (preliminary analysis).

	Behavioural intention	*Attitude*	*Social pressure*
Behavioural intention	-		
Attitude	0.47**	-	
Subjective norm	0.46**	0.52**	-
Perceived control	0.29**	0.07	0.32**

**Correlation significant at the 0.01 level (2-tailed).

Table E12. Linear regression of behavioural intentions onto psychological measures adjusting for the clustering in the data for offer of contraceptive supplies at discharge (preliminary analysis).

	Regression coefficient (B)	*Standardised regression coefficient (Beta)*	*95% CI*	*p*
Attitude	0.39	0.34	0.18, 0.61	<0.001
Subjective norm	0.28	0.21	0.02, 0.53	0.03
Perceived control	0.16	0.20	0.03, 0.28	0.02

Appendix 6F. Model structured case record

Initial assessment

Abortion care: structured clinical record

Date of appointment
Consultant
Contact permission GP Yes / No Home Yes / No Tel contact

Patient address and personal details

General history

Parity
Obstetric history
Previous medical history
Family history
Current medication
Smoker Yes / No
Allergy / sensitivity

Pregnancy counseling

LMP Cycle
Current contraception Reason contraceptive failed Planned contraception
Reason for request of induced abortion

General examination

Pelvic examination

Investigations

Assessment of gestation

Clinical: Ultrasound:

Date of last smear:

Result: Smear taken?

- ❑ FBC
- ❑ Group & save
- ❑ Chlamydia

Explanation of procedures and risks

- ❑ Procedure explained
- ❑ Around 1 in 1000 for:
  Haemorrhage
  Uterine perforation (surgical)
  Failed surgical or medical abortion
- ❑ Around 1 in 100 for cervical trauma
- ❑ Around 1 in 10 for infection
- ❑ Uncomplicated procedure no effect on future reproductive outcomes (infertility or preterm delivery)

- ❑ Need for further counselling?
- ❑ Certificate A
- ❑ Printed information issued?

Other remarks

Signature

Date

Method of abortion and arrangements

1st trimester MTOP	
Date attending for mifepristone	/ /
Date returning for admission	/ /
2nd trimester MTOP	
Date attending for mifepristone	/ /
Date returning for admission	/ /
STOP + misoprostol	
Admission date	/ /

Admission for procedure

Medical abortion: first visit

Date / /

❑ Consent

Mifepristone 200mg

Information given

- ❑ Phone ward only if vomited within 2 hours
- ❑ Paracetamol based analgesia only for pain
- ❑ Sanitary towels only for bleeding
- ❑ 1% risk of miscarriage – contact GP / ward
- ❑ Avoid alcohol and / or smoking
- ❑ Admission letter

Medical abortion: second visit

1st trimester

Date / /

Misoprostol 800 micrograms (4 X 200 microgram tabs) vaginally

❑ Products of conception seen?

If not, arrange follow up within 2 weeks

2nd trimester

Date / /

Misoprostol 800 micrograms (4 X 200 microgram tabs) vaginally, then misoprostol 400 micrograms orally every hours to a maximum of 4 oral doses

❑ Fetus seen? ❑ Placenta seen?

Surgical abortion

- ❑ Consent
- ❑ Cervical preparation: Misoprostol 400 micrograms vaginally, 3 hours prior to surgery (or Mifepristone)

Other prescriptions written up (surgical or medical)

- ❑ Antibiotic prophylaxis (Azithromycin 1G *or* Metronidazole 1G PR; Doxycycline 100mg BD oral 7days
- ❑ Analgesia
- ❑ Anti-emetic

Other remarks

After care

Anti-D

❑ Required? ❑ Given?

Contraception

Method

Immediate supply	Subsequent provision
❑ Hospital	❑ FPC
❑ FPC	❑ GP
❑ GP	❑ Other

Discharge advice

❑ Written discharge advice (including contact details) given?

Follow up offered

	Weeks
❑ GP	
❑ FPC	
❑ Gynaecology ward	
❑ Gynaecology clinic	
❑ GUM	

Medical termination

Dear Dr

The above patient was admitted to ..... on ..... under the care of ..... and underwent **medical termination of pregnancy**.

- ❑ The products of conception were complete
- ❑ The products were not seen / incomplete and she has been given an appointment to attend for follow-up on ..... She is aware of the importance of follow up.
- ❑ An evacuation of uterus was performed under GA

Chlamydia result

- ❑ Negative
- ❑ Positive, antibiotics were administered prior to discharge, and we have recommended that she attend GUM for follow up and contact tracing.
- ❑ Equivocal – action taken .....
- ❑ Not known – Action taken .....

Contraception

Chosen method

Immediate supply: hospital / FPC / GP

Subsequent provision: FPC / GP / Other

Blood group ..... **Anti-D .....** **Next cervical smear due .....**

We have recommended that the patient attend for follow up with her **general practitioner / family planning clinic** (delete as appropriate) within ..... weeks. This is to check that the abortion is complete, the use of contraception, the appropriate treatment of infection, contact tracing (where relevant), and general well being.

Yours sincerely

(Name and designation)

Surgical termination

Dear Dr

The above patient was admitted to ..... on ..... under the care of ..... and underwent **surgical termination of pregnancy**.

Chlamydia result

- ❑ Negative
- ❑ Positive, antibiotics were administered prior to discharge, and we have recommended that she attend GUM for follow up and contact tracing.
- ❑ Equivocal – action taken .....
- ❑ Not known – Action taken .....

Contraception

Chosen method:

Immediate supply: hospital / FPC / GP

Subsequent provision: FPC / GP / Other

Blood group ..... **Anti-D .....** **Next cervical smear due .....**

We have recommended that the patient attend for follow up with her **general practitioner / family planning clinic** (delete as appropriate) within ..... weeks. This is to check that the abortion is complete, the use of contraception, the appropriate treatment of infection, contact tracing (where relevant), and general well being.

Yours sincerely

(Name and designation)

Appendix 6G. Frequently asked questions

The clinical guideline, *The care of women requesting induced* abortion, was launched in March 2000. Subsequently, a national audit of abortion care was initiated by the Scottish Programme for Clinical Effectiveness in Reproductive Health (SPCERH) at the end of 2000. The audit results were fed back to participating gynaecology units at local meetings between June and July 2001.

The rationale behind or feasibility of several guideline recommendations were questioned during feedback. Not all of these issues could be addressed in full during the meetings. This paper responds further to some of the questions raised. However, it is recognised that many clinicians or units may have legitimate reasons for not following certain recommendations in part or in full.

What are the benefits of offering an assessment appointment within five days of referral? The earlier in pregnancy an abortion is performed, the lower the risk of complications. The absolute risk of complications at the time of abortion is low (0.7%) (1). The risk of serious complications increases 1.4 times for every 2 week increment in gestation beyond 12 weeks (2).

It has also been suggested that efforts to minimise the time between initial referral and the abortion procedure may pressurise some women to reach a decision (to have an abortion) quickly. Studies on the psychological aspects of induced abortion indicate that the majority of women decide early to have an abortion (3-6).

Setting a target of 5 days from referral to appointment is not feasible for units running weekly clinics. Yet, 38% of women in Scotland need to wait longer than 7 days for an assessment appointment. In 1992, a survey of Scottish gynaecologists (92% response rate), 81% agreed that a 'referral to assessment appointment' interval of 5 days represented an appropriate criterion for good quality care (7).

What some units have done or intend to do

- Eight out of thirteen units that received audit data have reorganised or are reviewing the organisation of their clinics.
- Some delays may be related to the failure of some practices and locum GPs to use the telephone referral service. As well as reminding GPs about quicker methods of referral, it might also be appropriate to direct reminders at practice managers (and perhaps practice secretaries as well).

Why enquire into cervical smear status? Three arguments were put forward against enquiring into cervical screening status during the pre-abortion assessment. First, women having abortions are generally younger and therefore at lower risk of cervical cancer than older age groups. Second, smears are more difficult to interpret during pregnancy. Third, taking smears may interfere with the primary care screening programme, especially if secondary care settings lack appropriate mechanisms for follow up of results.

The guideline does not suggest taking 'opportunistic' smears that would disrupt the screening programme; rather, that a smear should be considered and taken only if it is overdue. Abortion care should be part of a holistic approach to sexual health services. Checking cervical smear status offers an opportunity to discuss the value of screening and explore any concerns with women whose smears are overdue. Women requiring a smear can be reminded to attend their own general practices following the abortion. A sub-group of women attending for abortion care may make poor use of preventative services and subsequently represent a high risk group for cervical cancer.

What some units have done or intend to do

- The commonest reasons suggested for low compliance with this recommendation were either accidental omission or not recording even if smear status had been checked.
- Nine out of thirteen units fed back audit data are now considering amending or introducing structured case sheets that would include a question on smear status.

What are the benefits of ensuring contraception provision at discharge? In 1999, 24% of 12,167 women undergoing induced abortion in Scotland had experienced at least previous one abortion [ISD data]. The offer or provision of contraception is an essential component of preventive care following abortion. Whilst few gynaecologists would disagree with this statement, 30% of women having abortions in Scotland were discharged without a contraception supply or device (from either hospital or primary care). Some units reported organisational barriers to the provision of contraception at discharge. However, our survey of units indicated that low provision of contraception was associated with doubts regarding the value or effectiveness of contraception provision at discharge.

On 'average' across Scotland, 500 women attend each gynaecology unit for abortion care per year. The box below outlines scenarios considering the potential benefits of increasing provision at discharge. Considered in the context of other 'numbers needed to treat' (e.g. use of antenatal steroids), provision of contraception at discharge may be highly effective. Individual gynaecologists might prefer to calculate the potential benefits using a different set of more optimistic or pessimistic assumptions.

Best case scenario	*Worst case scenario*
If an additional 20% of women received contraception at discharge, 10% might still be using it by one year. Assuming that actually using contraception might prevent an unwanted pregnancy in one half of these women (compared with nothing), then a further unwanted pregnancy will be prevented in 5% of women who originally attended for abortion. This would translate roughly into 25 unwanted pregnancies prevented each year by each gynaecology unit (or *600 across Scotland*).	If an additional 10% of women received contraception at discharge, 2% might still be using it by one year. Assuming that actually using contraception might prevent an unwanted pregnancy in one half of these women (compared with nothing), then a further unwanted pregnancy will be prevented in 1% of women who originally attended for abortion. This would translate roughly into 5 unwanted pregnancies prevented each year by each gynaecology unit (or *120 across Scotland*).

Why offer a follow-up appointment within 2 weeks of discharge? The guideline suggests that women are offered a follow up appointment with either the abortion service or referring doctor. Doubts were expressed over both the value of providing routine follow up and the appropriateness of the suggested timing (2 weeks). Reasons for offering follow up include:

- Provision of counselling and reinforcement relating to contraceptive use – especially for women experiencing early problems when starting a new method of contraception;
- Detection of post-abortion infection;
- Exclusion of on-going pregnancy – for either medical or a smaller proportion of surgical cases.

The main rationale behind suggesting an interval of 2 weeks is that attendance rates for follow-up are likely to decline over longer periods of time. The costs of offering follow-up need to be balanced against those of not detecting failed procedures. Incomplete and failed procedures account for approximately half of complaints related to induced abortions (8). In a previous survey of women undergoing abortion in Scotland, 83% felt that a follow-up appointment was worthwhile (9).

General practitioners or family planning doctors can provide follow up care as required. If so, gynaecology units should consider incorporating an explicit statement in discharge letters concerning who is providing and the rationale for follow up.

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Appendix 7A. Membership of ImpACT Steering Group

Name	Title	Organisation
Alison Bigrigg	Consultant / Director, Family Planning and Well Women Services	Greater Glasgow Primary Care NHS Trust
Andrew Calder	Professor of obstetrics and gynaecology	Department of Reproductive and Developmental Sciences, University of Edinburgh
James Chalmers	Consultant in public health medicine	Information and Statistics Division, NHS in Scotland
Robbie Foy	MRC / CSO training fellow in health services research	Scottish Programme for Clinical Effectiveness in Reproductive Health (SPCERH), University of Edinburgh
Anna Glasier	Consultant / Director, Family Planning and Well Women Services	Lothian Primary Care NHS Trust
Jeremy Grimshaw	Programme Director, Health Services Research Unit, University of Aberdeen. (Currently: Director of the Clinical Epidemiology Programme Ottawa Health Research Institute and Director of the and Centre for Best Practices, Institute of Population Health, University of Ottawa)	Health Services Research Unit, University of Aberdeen
Anja Guettinger	Senior House Officer in obstetrics and gynaecology	South East Scotland Rotation
Gillian Penney	National Coordinator and clinical senior lecturer	SPCERH, Aberdeen Maternity Hospital
Craig Ramsay, HSRU, University of Aberdeen	Senior statistician	Health Services Research Unit, University of Aberdeen
Sally Stearns	Senior research fellow	Health Economics Research Unit, University of Aberdeen
Anne Walker	Senior Behavioural Scientist	Health Services Research Unit, University of Aberdeen

Appendix 7B. Case note data collection form

1	**Hospital code number**			

2	Patient study number			

IMPACT

Improving Abortion Care Trial

Data collection form

Scottish Programme for Clinical Effectiveness
in Reproductive Health (SPCERH)

Where appropriate, please mark boxes with a *cross*.

X

Referral and initial assessment

3 Date of referral on GP's letter or of self-referral to family planning clinic

d	d	m	m	y	y

4 Who referred the patient for the gynaecological assessment appointment (where the procedure was arranged)?

General practitioner		= 1
Family planning clinic		= 2
Self		= 3
Other		= 4

(Cross appropriate box)

Other specified source of referral

_____

5 Venue where gynaecological assessment appointment took place (i.e. where procedure was arranged)

Hospital outpatient clinic		= 1
Family planning clinic		= 2

6 Date patient attended for above appointment (Q5)

d	d	m	m	y	y

7 Patient age at time of referral (years)

8 Number of live and still births

9 Number of miscarriages and previous induced abortions

10 Date of LMP (Place an 'XX' in the box if any figure is unknown)
11

d	d	m	m	y	y

11 **Best estimate** of gestation at date of assessment appointment at gynaecology outpatients OR family planning clinic (completed weeks; use corrected gestation following scan on day of assessment appointment if available)

Pre-abortion investigations

12 Haemoglobin concentration checked?

Yes		= 1
No		= 2

(Cross appropriate box)

13 Blood group (ABO) checked?

Yes		= 1
No		= 2

14 Cross matching performed?

Yes		= 1
No		= 2

15 Rhesus (Rh) status checked?

Rh +ve		= 1
Rh –ve		= 2
No record		= 3

16 Enquiry about date of last cervical smear?

Yes		= 1
No *(go to Q18)*		= 2

17 If yes, smear taken within previous 3 years? (Statements of 'smear up to date' acceptable as a response.)

Yes		= 1
No		= 2
No record		= 3

18 Cervical smear taken at the clinic?

Yes		= 1
No		= 2

19 Ultrasound scan undertaken?

Yes		= 1
No *(Go to Q21)*		= 2

20 If yes, stated reason why

Stated as gestation in doubt		= 1
Suspected extra-uterine pregnancy		= 2
Routine OR not recorded		= 3

(Cross appropriate box)

21 Screening for lower genital tract organisms and/or antibiotic prophylaxis*

Genital tract screening AND antibiotics given		= 1
Genital tract screening ONLY		= 2
Antibiotics given ONLY *(go to question 23)*		= 3
Not recorded *(go to question 23)*		= 4

*Screening includes either taking a genital tract swab for culture OR sending urine for Ligase Chain Reaction (LCR). Antibiotic treatment may be recorded in case notes, the day case form, or drug kardex.)

22 Results of screening

Positive test or significant growth* AND given antibiotics		= 1
Positive test or significant growth BUT NOT given antibiotics		= 2
Other or no significant growth		= 3
Result not found nor recorded		= 4

*Significant or positive test results are for one or more of: Chlamydia trachomatis, Neisseria Gonorrhoea or bacterial vaginosis.

The abortion procedure

(Information on drugs prescribed may be found in the case notes, day case form, or drug kardex.)

23 Date termination procedure commenced (surgical or mifepristone component of medical abortion)

d	d	m	m	Y	y

24 Date of admission for abortion (surgical or Gemeprost / misoprostol component)

d	d	m	m	y	y

25 Estimated gestation at date of termination (completed weeks)

26 Date of discharge

d	d	m	m	y	y

27 Method of abortion

Suction termination *(Go to Q31)*		= 1
Medical abortion *(Continue to Q28)*		= 2

Medical abortions

28 Use of surgical evacuation following medical abortion

Yes – record of incomplete abortion		= 1
Yes – *no* record of incomplete abortion		= 2
No		= 3

29 Medical abortion: Dose of mifepristone

200 mg		= 1
400 mg		= 2
600 mg		= 3

30 Medical abortion: Prostaglandin used

Misoprostol		= 1
Gemeprost 0.5 g		= 2
Gemeprost 1 g		= 3

Now go to question 35

Surgical abortions

31 Type of anaesthetic recorded

General anaesthetic		= 1
Local anaesthetic		= 2

32 Cervical preparation for surgical termination

Mifepristone		= 1
Misoprostol		= 2
Gemeprost		= 3
Laminaria		= 4
Not recorded		= 5

33 Most senior grade of operator present (as written on operation note)

Consultant		= 1
Staff grade		= 2
Specialist registrar		= 3
SHO		= 4
Unknown		= 5

34 Grade of any other operator present

Consultant		= 1
Staff grade		= 2
Specialist registrar		= 3
SHO		= 4
Unknown or none		= 5

All abortions

35 If Rhesus negative, was anti-D given?

Yes		= 1
Not recorded		= 2
Not required		= 3

36 Immediate post or peri-operative complications documented

Suspected or actual uterine perforation *(go to question 37)*		= 1
Haemorrhage (more than 500 ml recorded) *(go to question 38)*		= 2
Cervical trauma requiring suture *(go to question 39)*		= 3
None of the above *(go to question 39)*		= 4

37 Procedure performed if uterine perforation suspected

Laparoscopy		= 1
Laparotomy		= 2
Both		= 3
None		= 4

38 Initial treatment given if haemorrhage occurs

Syntometrine		= 1
Other (specify)		= 2

Other specified treatment _____

After care

39 Contraceptive plan documented by time of discharge

Yes (including any plan recorded at assessment appointment)		= 1
Not recorded		= 2

40 Was it documented that referring doctor (family planning or GP) had already provided contraceptive supplies?

Yes		= 1
No *(Go to Q42)*		= 2

41 If yes, state type of contraceptive supplied

Oral contraceptive		= 1
Condoms		= 2
Other (specify)		= 3

Other specified treatment _____

42 If no, were contraceptive supplies documented as being provided by the hospital *before or at the time of discharge*? (i.e. exclude later return appointments for sterilisation or insertion of IUCDs, etc.)

Yes		= 1
No		= 2

43 If yes, type of contraceptive supplied *(cross all that apply)*

Oral contraceptive		= 1
Condoms		= 2
IUCD or IUS (Mirena)		= 3
Cap fitted		= 4
Depot progestogen (Depo-Provera)		= 5
Sterilised		= 6
Implanon		= 7
Emergency contraception		= 8
Other (specify)		= 9

Other specified treatment _____

44 Documented follow-up arrangements *as stated in the case notes or discharge letter* *(cross all that apply)*

Hospital		= 1
Referring doctor		= 2
GUM clinic		= 3
None recorded		= 4

45 What was the suggested interval to follow up?

1 week		= 1
2 weeks		= 2
3 weeks		= 3
4 weeks		= 4
6 weeks		= 5
None or none stated		= 6
Other (please specify)		= 7

Other specified _____

Initials of data collector:	*Date:*

Thank you. Please return in batches of 5 – 10 to:

Robbie Foy
SPCERH
Department of Reproductive and Developmental Sciences
University of Edinburgh
37 Chalmers Street

Edinburgh EH3 9ER

Appendix 7C. Case identification form

CONFIDENTIAL

Hospital: Data collector:

Study number	*Hospital identification number*	*Name*	*Consultant initials*
1			
2			
3			
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Appendix 7D. Patient questionnaire

Scottish survey of abortion care

Name of Unit

PATIENT QUESTIONNAIRE

Please read the 'Information for patients' before looking at this questionnaire. This questionnaire asks about your experience of having an abortion. All information collected about you will be kept anonymous and strictly confidential. Therefore you cannot be identified from this questionnaire. You may decline to answer any question in the questionnaire without giving a reason. If you decide to help us by filling in this questionnaire, please do so now or shortly after leaving the hospital.

THE FOLLOWING QUESTIONS CONCERN ARRANGEMENTS MADE FOR YOUR ABORTION

1	Most women having an abortion first see their general practitioner or family planning doctor before being referred to a hospital clinic or a specialist within the family planning centre. Did this happen to you?	*Please circle response that best fits your experience* Yes No (please go to question 3) Not sure	 1 2 3
2	After seeing your general practitioner or family planning doctor, how long did you wait to attend your first hospital or specialist appointment?	Approximately _____ days	
3	After this assessment appointment with the gynaecologist or family planning doctor, how long did you wait to attend the hospital for your abortion procedure? If you had a medical (drug) abortion only (no operation and general anaesthetic), this refers to how long you waited until the day you received your first drug treatment.	Approximately _____ days	

THE FOLLOWING QUESTIONS CONCERN HOW SATISFIED YOU ARE WITH ANY COUNSELLING YOU RECEIVED

4	There was too much emotional talk	*Please circle response that best fits your experience* Strongly agree Agree Neither agree or disagree Disagree Strongly disagree	 1 2 3 4 5
5	There was too much medical talk	Strongly agree Agree Neither agree or disagree Disagree Strongly disagree	1 2 3 4 5
6	The staff asked too many questions	Strongly agree Agree Neither agree or disagree Disagree Strongly disagree	1 2 3 4 5
7	During your clinic appointments, did you have enough time and help in reaching your decision to have an abortion?	Yes No	1 2
8	Do you feel **now** that your decision was right for you?	Yes No	1 2

THE FOLLOWING QUESTIONS CONCERN HOW SATISFIED YOU ARE WITH THE CARE YOU RECEIVED

9	The clinical care I received was excellent	*Please circle response that best fits your experience* Strongly agree Agree Neither agree or disagree Disagree Strongly disagree	 1 2 3 4 5
10	My confidentiality was protected	Strongly agree Agree Neither agree or disagree Disagree Strongly disagree	1 2 3 4 5
11	The staff treated me with respect	Strongly agree Agree Neither agree or disagree Disagree Strongly disagree	1 2 3 4 5
12	The staff were professional and thorough	Strongly agree Agree Neither agree or disagree Disagree Strongly disagree	1 2 3 4 5
13	The staff treated me as a whole person	Strongly agree Agree Neither agree or disagree Disagree Strongly disagree	1 2 3 4 5

14	The staff weren't afraid to discuss emotional issues (about how you felt).	Strongly agree Agree Neither agree or disagree Disagree Strongly disagree	1 2 3 4 5
15	There are some things about the medical care I received that could be better	Strongly agree Agree Neither agree or disagree Disagree Strongly disagree	1 2 3 4 5
16	Some women having an abortion may be suitable for either medical (*drug treatment only*) or surgical (*requiring general anaesthetic*) abortion methods. Were you offered a choice of abortion method?	Yes No Can't recall / not sure	1 2 3
17	What type of abortion did you have?	Surgical abortion Medical abortion Not sure	1 2 3

THE FOLLOWING QUESTIONS CONCERN INFORMATION GIVEN TO YOU.

18	Were you given a leaflet about abortion in your local clinic or hospital before the procedure?	Yes No Can't recall / not sure	1 2 3
19	Did the doctors or nurses talk to you possible problems or complications after the abortion?	Yes No Can't recall / not sure	1 2 3
	Major complications are rare following abortion. Were any of the following possible complications mentioned to you?		
20	Excessive bleeding following the abortion (haemorrhage)	Yes No Can't recall / not sure	1 2 3
21	Damage to the uterus, or womb, requiring a more major operation (uterine perforation; this is only relevant to surgical abortions)	Yes No Can't recall / not sure Not relevant – I had a medical abortion	1 2 3 4
22	Failure of the abortion method (and need for another abortion procedure)	Yes No Can't recall / not sure	1 2 3
23	Pelvic infection	Yes No Can't recall / not sure	1 2 3
24	While you were at hospital, were you given a leaflet or letter describing any symptoms you may experience after the abortion, including those that should make you seek medical advice urgently?	Yes No Can't recall / not sure	1 2 3

THE FOLLOWING QUESTIONS CONCERN ARRANGEMENTS MADE FOLLOWING THE ABORTION.

25	Has a follow up appointment been arranged for you?	No, not offered	1
		No, I was offered but did not want a further appointment	2
		Yes, at the hospital	3
		Yes, at the family planning clinic	4
		Yes, with my GP	5
26	If yes, how many weeks after the abortion has an appointment been arranged for?	Approximately _____ weeks	
27	While you were at hospital, did anyone discuss your future plans for contraception with you?	Yes	1
		No	2
		Can't recall / not sure	3
28	While you were at hospital, did anyone offer to provide you with a method of contraception before going home?	Yes	1
		No	2
		No need. I already have contraception through my GP or family planning clinic	3
		Can't recall / not sure	4
29	What are you going to do about contraception from *now*?	I am on the contraceptive pill	1
		I have had a contraceptive injection or implant	2
		I have an IUD fitted (also known as the coil)	3
		We / my partner uses condoms	4
		I have been sterilised	5
		My partner has been sterilised	6
		I use a cap / diaphragm	7
		Nothing, but I plan to start soon	8
		Nothing, I don't need contraception now	9
		I use another method (please describe below)	10

THE FINAL QUESTIONS ARE ABOUT YOU

30	What is your age?	..... Years	
31	How many weeks pregnant were you at the time of your abortion?	..... Weeks	
32	We wish to make general comparisons between women participating in this survey and all women in Scotland having an abortion. This can be done *without* revealing your address or identity if you are able to provide your postcode WITHOUT THE LAST 2 LETTERS. For example If your postcode has SIX numbers and letters, miss out the last two letters, *EH3 9ER becomes EH3 9* If your postcode has SEVEN numbers and letters, miss out the last 2 letters: *EH13 9ER becomes EH13 9*	My postcode without the last 2 letters is _____ Or, tick this box if you do not know your postcode [ ]	

PLEASE CHECK THAT YOU HAVE ANSWERED ALL OF THE QUESTIONS AND RETURN THE QUESTIONNAIRE IN THE STAMPED ADDRESSED ENVELOPE.

Thank you for your help

Appendix 7E. Action list following outreach educational meetings

1	**Name of unit**		
	Educational meeting		
2	Length		
3	Attendance (separate sheet for details of staff discipline and grade)	Consultants	
		Staff grade	
		Associate specialists	
		SpR	
		SHO	
		Midwifery sisters	
		Staff midwives	
		Nursing sisters	
		Staff nurses	
		Secretaries	
		Medical students	
4	Any other costs associated with the meeting, e.g. consumables		
	Action plan meeting		
5	Length		
6	Attendance		
	Action decided or suggested		
7			
8			
9			
10			
11			
12			
11			

RF comments

Appendix 7F. Survey of lead gynaecologists for process and economic evaluation

Gynaecology unit	
Date	
Interviewee	
Other interviewees	
Notes	

1. Organisation of clinic appointments during May to November 2001? YES / NO

If yes, what changes occurred in the structure or process of abortion care itself? (Probe for details on time and resource implications.)			
CHANGE in clinic, ward or theatre time			
CHANGE in staff time and composition			
Training and education			
Medical equipment, e.g. drugs			
Administrative resources, e.g. computing			
Other			
How much time was spent negotiating the change, e.g. meetings, paperwork?	Activity	Staff type and grade	Time (hrs)
Were there any costs or benefits to other services as a result of these processes or changes?			

2. Recording of cervical smear status during May to November 2001? YES / NO

If yes, what changes occurred in the structure or process of abortion care itself? (Probe for details on time and resource implications.)			
CHANGE in clinic, ward or theatre time			
CHANGE in staff time and composition			
Training and education			
Medical equipment, e.g. drugs			
Administrative resources, e.g. computing			
Other			
How much time was spent negotiating the change, e.g. meetings, paperwork?	Activity	Staff type and grade	Time (hrs)
Were there any costs or benefits to other services as a result of these processes or changes?			

3. Strategies to minimise risk of post-abortion infection (antibiotic prophylaxis or screening) during May to November 2001? YES / NO

If yes, what changes occurred in the structure or process of abortion care itself? (Probe for details on time and resource implications.)			
CHANGE in clinic, ward or theatre time			
CHANGE in staff time and composition			
Training and education			
Medical equipment, e.g. drugs			
Administrative resources, e.g. computing			
Other			
How much time was spent negotiating the change, e.g. meetings, paperwork?	Activity	Staff type and grade	Time (hrs)
Were there any costs or benefits to other services as a result of these processes or changes?			

4. Use of misoprostol in place of gemeprost during May to November 2001? YES / NO

If yes, what changes occurred in the structure or process of abortion care itself? (Probe for details on time and resource implications.)			
CHANGE in clinic, ward or theatre time			
CHANGE in staff time and composition			
Training and education			
Medical equipment, e.g. drugs			
Administrative resources, e.g. computing			
Other			
How much time was spent negotiating the change, e.g. meetings, paperwork?	Activity	Staff type and grade	Time (hrs)
Were there any costs or benefits to other services as a result of these processes or changes?			

5. Provision of contraception at discharge during May to November 2001? YES / NO

If yes, what changes occurred in the structure or process of abortion care itself? (Probe for details on time and resource implications.)			
CHANGE in clinic, ward or theatre time			
CHANGE in staff time and composition			
Training and education			
Medical equipment, e.g. drugs			
Administrative resources, e.g. computing			
Other			
How much time was spent negotiating the change, e.g. meetings, paperwork?	Activity	Staff type and grade	Time (hrs)
Were there any costs or benefits to other services as a result of these processes or changes?			

6. Offer of follow-up at discharge during May to November 2001? YES / NO

If yes, what changes occurred in the structure or process of abortion care itself? (Probe for details on time and resource implications.)			
CHANGE in clinic, ward or theatre time			
CHANGE in staff time and composition			
Training and education			
Medical equipment, e.g. drugs			
Administrative resources, e.g. computing			
Other			
How much time was spent negotiating the change, e.g. meetings, paperwork?	Activity	Staff type and grade	Time (hrs)
Were there any costs or benefits to other services as a result of these processes or changes?			

7. Can you recall ANY OTHER changes to the way abortion care is provided in your unit within the past 6 months?

If yes, please list main changes (*one box or page for each change*)

Change made. (Probe for details on time and resource implications.)			
CHANGE in clinic, ward or theatre time			
CHANGE in staff time and composition			
Training and education			
Medical equipment, e.g. drugs			
Administrative resources, e.g. computing			
Other			
How much time was spent negotiating the change, e.g. meetings, paperwork?	Activity	Staff type and grade	Time (hrs)
Were there any costs or benefits to other services as a result of these processes or changes?			

8. Can you recall ANY OTHER changes to the way abortion care is provided in your unit within the past 6 months?

Change made. (Probe for details on time and resource implications.)	(Unplanned) greater input to abortion care from current batch of SHOs		
CHANGE in clinic, ward or theatre time			
CHANGE in staff time and composition			
Training and education			
Medical equipment, e.g. drugs			
Administrative resources, e.g. computing			
Other			
How much time was spent negotiating the change, e.g. meetings, paperwork?	Activity	Staff type and grade	Time (hrs)
Were there any costs or benefits to other services as a result of these processes or changes?			

Appendix 7G. Outcomes for post-intervention case note review

Organisation and access

Recommendation	*Database analysis*
Offer of appointment with a gynaecologist within five days of referral (ideal; primary outcome)	Denominator = all women Numerator = 6 (date assessment) minus 3 (referral date) Should equal 5 days or less for compliance
Offer of appointment with a gynaecologist within 14 days of referral (acceptable)	Denominator = all women Numerator = 6 (date assessment) minus 3 (referral date) Should equal 14 days or less for minimum standard
Abortion within seven days of the decision to proceed being agreed (ideal)	Denominator = all women Numerator = 23 (date termination) minus 6 (date assessment) Should equal 7 days or less for compliance
Abortion within 14 days of the decision to proceed being agreed (acceptable)	Denominator = all women Numerator = 23 (date termination) minus 6 (date assessment) Should equal 14 days or less for minimum standard
As a minimum standard, no individual woman need wait longer than three weeks from her initial referral to the time of her abortion.	Denominator = all women Numerator = 23 (date termination) minus 3 (referral date) = LESS than 21 days
Management of induced abortion as day case unless contra-indicated	Denominator = all women Numerator = 26 (date discharge) minus 24 (date admission) Should equal zero for compliance

Pre-abortion management

Recommendation	*Database analysis*
Appropriate blood tests performed	Denominator = all women Numerator = Compliance if ALL of the following met: 12 (haemoglobin) = 1 **AND** 13 (blood group) = 1 **AND** 15 (rhesus) = 1 OR 2
Avoidance of routine cross-matching	Denominator = all women Numerator = 14 (cross matching) = 2
Ascertainment of cervical cytology history (primary outcome)	Denominator = 7 (age) > 19 years Numerator = 16 (smear enquiry) = 1
Offer of cervical smear if indicated and appropriate follow up action	Denominator (women 20 years or over who have had a smear enquiry) = 7 (age) > 19 years *AND* 16 (smear enquiry) = 1 Numerator (it is appropriate for women who have NOT had a smear in the previous 3 years to have a smear taken. It is also appropriate for women who have had a smear taken in previous 3 years NOT to have a smear taken) = 17 (smear <3 years) = 1 *AND* 18 (smear taken) = 2 **OR** 17 (smear <3 years) = 2 *AND* 18 (smear taken) = 1

Avoidance of ultrasound scanning unless indicated (gestation in doubt or suspected extra-uterine pregnancy)	Proportion of women not having ultrasound OR having a recorded indication Denominator = all women Numerator = **EITHER** 19 (ultrasound) = 2 **OR** 19 (ultrasound) = 1 *AND* 20 (reason) = 1 OR 2
Antibiotic prophylaxis or screening for lower genital tract organisms (primary outcome)	Denominator = all women Numerator = 21 (GU screening) = 1 OR 3 **OR** 21 (GU screening) = 2 *AND* 22 (Results of screening) = 1 OR 3

Procedures

Recommendation	*Database analysis*
Preferential use of medical abortion at gestations < 7 (and up to 9) weeks	Denominator (all women with gestation less than 7 weeks) = 25 (estimated gestation at abortion) < 7 weeks Numerator = 27 (method of abortion) = 2
For early medical abortion, a dose of 200mg of mifepristone, in combination with a prostaglandin is adequate	Denominator (all women having an early medical abortion) = 25 (estimated gestation at abortion) < 10 weeks *AND* 27 (method abortion) = 2 Numerator = 29 (dose mifepristone) = 1
Misoprostol cost-effective alternative to gemeprost (in early medical abortion, cervical priming and mid-trimester medical abortion) (primary outcome)	**For medical abortions** Denominator is all women who have had a medical abortion up to 24 weeks, i.e. 25 (estimated gestation at abortion) < 25 weeks *AND* 27 (Method abortion) = 2 Numerator is: 30 (Prostaglandin) = 1 **For surgical abortions** Denominator is surgical abortions where priming was used, i.e. 27 (Method abortion) = 1 AND 32 (Cervical preparation) = 1, 2, 3, or 4 Numerator is: 32 (Cervical preparation) = 2 Then add both of these sums together for composite measure of compliance

Use of conventional suction termination at gestations of 7-15 weeks if appropriate or preferred	Denominator (all women between 7 and 15 weeks gestation inclusive) = 25 (estimated gestation at abortion) 7 to 15 weeks inclusive Numerator is: 27 (Method abortion) = 1
Availability of local rather than general anaesthesia for suction termination	Denominator is 27 (method abortion) = 1 *AND* 25 (Gestation) = 7 to 15 weeks inclusive Numerator: 31 (type of anaesthetic) = 2
Routine use of cervical priming for women aged under 18 or > 10 weeks gestation	Denominator (all women having surgical abortions aged under 18 or at over 10 weeks gestation), ie. 27 (method abortion) = 1 ***AND at least one of*** 7 (Age) LESS THAN 18 years ***OR*** 25 (Gestation) GREATER THAN 10 weeks Numerator (use of cervical priming) = 32 (Cervical preparation) = 1, 2, 3 or 4
200mg of mifepristone plus prostaglandin in mid-trimester medical abortion	Denominator = 25 (estimated gestation at abortion) 13 to 24 weeks inclusive *AND* 27 (method abortion) = 2 Numerator = 29 (dose mifepristone) = 1
Avoidance of routine surgical evacuation of uterus following mid-trimester medical abortion unless indicated	Denominator is 27 (method of abortion) = 2 *AND* 25 (estimated gestation at abortion) 13 to 24 weeks inclusive Numerator is 28 (use of surgical evac) must = 1 OR 3

Mid-trimester abortion using D&E by specialist practitioners with access to necessary instruments and sufficiently large caseload	Denominator: 25 (gestation at abortion) > 15 weeks *AND* 27 (method of abortion) = 1, Numerator: 32 (Cervical preparation) = 1, 2, 3 or 4 (for surgical abortions) *AND* 33 (most senior operator) = 1 or 2
Alternative use of medical abortion at > 15 weeks gestation	Denominator is 25 (gestation at abortion) > 15 weeks, Numerator is: 27 (method of abortion) = 2

Managing complications

Recommendation	*Database analysis*
Oxytocics are effective in reducing intra-operative blood loss	Denominator is 27 (method of abortion) = 1 *AND* 36(complications) = 2 Numerator is 38 (initial treatment) = 1
In cases of suspected uterine perforation laparoscopy is the investigation of choice	Denominator is 27 (method of abortion) = 1 *AND* 36(complications) = 1 Numerator is 37 (procedure) must = 1 OR 3

After care

Recommendation	*Database analysis*
Administration of Anti-D IgG to all non-sensitised RhD negative women following abortion	Denominator = 15 (rhesus) = 2 Numerator = 35 (anti-D) = 1
Offer of follow-up appointment (with service or referrer) within 2 weeks of abortion	Denominator = all women Numerator = 44 (FU venue) = NOT 4, *AND* 45 (Suggested interval) = 1 or 2
Discussion of future contraception prior to discharge	Denominator is all women Numerator = 39 (contraceptive plan) = 1
Offer of contraceptive supplies if required prior to discharge (primary outcome)	Denominator = all women Numerator = 40 (Referrer supply) = 1 ***OR*** 42 (Hospital supply) = 1 ***OR*** Both of above
Sterilisation can safely be performed at time of induced abortion (with higher rates of failure and regret)	Denominator = all women Numerator = 43 (type supplied) = NOT 6 Inverse of baseline analysis to demonstrate compliance rather than non-compliance
Safety and effectiveness of IUCD insertion immediately following induced abortion	Denominator = all women Numerator = 43 (type supplied) = 3

Appendix 7H. Outcomes for ImpACT post-intervention patient survey

Organisation and access

Recommendation	*Database analysis*
Offer of appointment with a gynaecologist within five days of referral (ideal; primary outcome)	Denominator: 1 (referring doctor) = 1 Numerator: 2 (first appointment) = 5 or less
Offer of appointment with a gynaecologist within 14 days of referral (acceptable)	Denominator: 1 (referring doctor) = 1 Numerator: 2 (first appointment) = 14 or less
Abortion within seven days of the decision to proceed being agreed (ideal)	Denominator: All cases Numerator: 3 (date procedure) = 7 or less
Abortion within 14 days of the decision to proceed being agreed (acceptable)	Denominator: All cases Numerator: 3 (date procedure) = 14 or less
As a minimum standard, no individual woman need wait longer than three weeks from her initial referral to the time of her abortion.	Denominator: 1 (referring doctor) = 1 Numerator: The sum of [2 (first appointment) AND 3 (date procedure)] = 21 or less

Information for women

Recommendation	*Database analysis*
Verbal advice must be supported by accurate, impartial printed information which the woman considering abortion can understand and may take away and read before the procedure	Denominator: all women Numerator: 18 (leaflet) = 1

Information for women and professionals should emphasise the duty of confidentiality by which, as for any form of health care, all concerned with the provision of induced abortion are bound	Denominator: all women Numerator: 10 (confidentiality) = 1 or 2
Professionals providing abortion services should possess accurate knowledge about possible complications and sequelae of abortion. This will permit them to provide women with the information they need in order to give genuinely informed consent	Denominator: all women Numerator: 19 (possible problems) = 1
Possible complications mentioned during counselling: haemorrhage	Denominator: all women Numerator: 20 (haemorrhage) = 1
Possible complications mentioned during counselling: uterine perforation	Denominator: 17 (type of abortion) = 1 Numerator: 21 (uterine perforation) = 1
Possible complications mentioned during counselling: failure	Denominator: all women 22 (failure) = 1
Possible complications mentioned during counselling: pelvic infection	Denominator: all women 23 (pelvic infection) = 1

Composite score for patient information • Based on meeting 5/5 of above criteria for surgical cases • Based on meeting 4/4 of above criteria (not Q21) for medical cases	For surgical cases Denominator: 17 (type of abortion) = 1 Numerator: ALL must = 1 19 (possible problems) 20 (haemorrhage) 21 (uterine perforation) 22 (failure) 23 (pelvic infection) For medical cases Denominator: 17 (type of abortion) = 2 Numerator: ALL must = 1 19 (possible problems) 20 (haemorrhage) 22 (failure) 23 (pelvic infection) Then add both together for overall score

Pre-abortion management

No items covered on patient questionnaire

Procedures

Recommendation	*Database analysis*
Ideally, abortion services must be able to offer a choice of recommended procedures for relevant gestation bands	Denominator: 31 (gestation) between 7 and 9 inclusive or 13 and 24 weeks inclusive Numerator: 16 (choice) = 1

Managing complications

No items covered on patient questionnaire

After care

Recommendation	*Database analysis*
After an abortion, women must be given a written account of the symptoms they may experience and a list of those that would make an urgent medical consultation necessary. They should be given a 24 hour help-line telephone number to use if they feel worried about pain, bleeding or high temperature	Denominator: all women 24 (leaflet) = 1
A follow-up appointment (either within the abortion service or with the referring clinician) within two weeks of the procedure should be offered to each patient following abortion	Denominator: all women **Numerator:** 25 (follow up appointment) = 3, 4 or 5 AND 26 (weeks) = 1 or 2
Before she is discharged following abortion, future contraception should have been discussed with each patient	Denominator: all women Numerator: 27 (contraceptive plan) = 1
Contraceptive supplies should have been offered if required. The chosen method of contraception should be initiated immediately following abortion (primary outcome)	Denominator: all women Numerator: 28 (contraception method) = 1 or 3
Sterilisation can safely be performed at the time of induced abortion. However combined procedures are associated with higher rates of failure and of regret	Denominator: all women Numerator: 29 (contraception now) = NOT 5
It is safe and effective to insert an IUCD for contraceptive use immediately following induced abortion	Denominator: all women Numerator: 29 (contraception now) = 3

Counselling process

Recommendation	*Database analysis*
There was too much emotional talk	4 (emotional) = mean response
There was too much medical talk	5 (medical) = mean response
The staff asked too many questions	6 (questions) = mean response
Summary score (used by Zapka et al)	Summary mean of above items for each case

Other questions about counselling

Recommendation	*Database analysis*
During your clinic appointments, did you have enough time and help in reaching your decision to have an abortion?	Denominator: all women Numerator: 7 (time) = 1

Do you feel **now** that your decision was right for you?	Denominator: all women Numerator: 8 (right decision) = 1

Staff competency

Recommendation	*Database analysis*
The clinical care I received was excellent	9 (clinical care) = mean
My confidentiality was protected (Duplicates earlier question about recommendation)	10 (confidentiality) = mean
The staff treated me with respect	11 (respect) = mean
The staff were professional and thorough	12 (professional) = mean
Summary score	Summary mean of above items for each case

Staff sensitivity

Recommendation	*Database analysis*
The staff treated me as a whole person	13 (whole person) = mean
The staff weren't afraid to discuss emotional issues (about how you felt).	14 (emotional) = mean
Summary score	Summary mean of above items for each case

Global rating of satisfaction

Recommendation	*Database analysis*
There are some things about the medical care I received that could be better	15 (could be better) = mean

Appendix 7l. Costing of ImpACT intervention

Audit and feedback			
Component or step	**Resources**	**Cost per hour (£)**	**Total (£)**
Planning of design and data collection	80 hours @ clinical research fellow (grade AM2)	25.40	2031.74
	8 hours @ clinical senior lecturer (non-consultant scale)	36.35	290.83
Liaison with 13 intervention units, e.g. to recruit data collectors	8 hours @ grade CN3 secretarial support	8.95	71.62
	40 hours @ clinical research fellow (grade AM2)	25.40	1015.85
	1 hour each for 13 local lead consultants	48.75	633.81
Training of data collectors: training day in Edinburgh	8 hours @ clinical research fellow (grade AM2)	25.40	203.17
	8 hours @ clinical senior lecturer (non-consultant scale)	36.35	290.83
	4 hours @ grade CN3 secretarial support	8.95	35.81
	8 hours of data collectors' time (intervention units only)		
	3 nursing sisters	18.86	452.62
	3 staff nurses	13.75	330.06
	5 medical secretaries	8.95	358.08
	4 hours of above data collectors' travel (estimated time of round trip)	142.59	570.37
	Travel expenses claimed for 11 data collectors @ £20 each		220.00
	Catering		100.00
Outreach training (for data collectors unable to attend training day)	2 visits @ 4 hours each of clinical research fellow (grade AM2)	25.40	203.17
	Estimated total of 15 hours travel time @ clinical research fellow (grade AM2)	25.40	380.95
	2 hours each of data collectors' time	142.59	285.19
	Catering		50.00
Printing and postage of data collection forms	1000 forms printed for intervention units		75.00
	Postage @ £5 per pack		65.00
Data collection	Average of 41 cases per unit @ £6 paid per form returned		3198.00
	Case note retrieval @ £1 per case note		533.00
Data entry	4 hours @ clinical research fellow (grade AM2)	25.40	101.59
	20 hours @ grade CN3 secretarial support	8.95	179.04
Data analysis	32 hours @ clinical research fellow (grade AM2)	25.40	812.80
	8 hours of statistician time	14.30	114.40
Preparation and dissemination of baseline audit reports	32 hours @ clinical research fellow (grade AM2)	25.40	812.80
	8 hours @ grade CN3 secretarial support	8.95	71.62
	4 hours @ clinical senior lecturer (non-consultant scale)	36.35	145.41
	Photocopying = 3p per sheet 1 report (45 pages) = £1.35 Postage £5 For 10 reports per unit		240.50
Total intervention cost			13341.00
Average cost per unit			1026.23

Identification of barriers			
Component or step	**Resources**	**Cost per hour (£)**	**Total (£)**
Outreach meetings with clinical directors	13 meetings, 1 hour per meeting @ clinical research fellow (grade AM2)	25.40	330.16
	Travel to 13 meetings, 2 hours per trip @ clinical research fellow (grade AM2)	25.40	660.32
	1 hour each for 13 local lead consultants	48.75	633.81
	8 hours analysis of findings @ clinical research fellow (grade AM2)	25.40	203.17
Staff survey preparation of questionnaire and survey	32 hours @ clinical research fellow (grade AM2)	25.40	609.52
	4 hours @ clinical senior lecturer (non-consultant scale)	36.35	145.41
	4 hours by behavioural scientist	21.68	86.73
Production and postage of 200 questionnaires	Photocopying = 5 sheets @ 3p each; £30 total Postage = 27p each; £54 total		84.00
Completion of questionnaires	147 questionnaires @ 20 minutes each		
	38 Consultants	48.73	617.31
	5 Staff Grades	31.74	52.91
	21Specialist Registrars	26.78	187.46
	23 SHOs	23.62	181.09
	17 Nursing and midwifery sisters	18.86	106.87
	43 Staff midwives and nurses	13.75	197.12
Data entry	12 hours @ grade CN3 secretarial support	8.95	107.42
Data analysis	8 hours by behavioural scientist	21.68	173.45
	8 hours @ clinical research fellow (grade AM2)	25.40	203.17
Total intervention cost			4579.92
Average cost per unit			352.30

Educational meetings			
Component or step	**Resources**	**Cost per hour (£)**	**Total (£)**
Preparation	13 meetings, 1 hour per meeting @ clinical research fellow (grade AM2)	25.40	330.16
Travel	13 meetings, 3 hours travel per meeting @ clinical research fellow (grade AM2)	25.40	990.48
	Direct travel costs @ £20 per meeting		260.00
Catering	£50 per meeting		650.00
Attendance at meetings	13 meetings, 1 hour per meeting @ clinical research fellow (grade AM2)	25.40	330.16
	1 hour attendance by clinical staff		4228.16
Costs of room	£50 per room for 13 meetings		650.00
Action planning meetings	13 meetings, 20 minutes per meeting @ clinical research fellow (grade AM2)	25.40	110.05
	20 minutes per meeting clinical staff		289.27
Preparation of FAQ sheet	8 hours @ clinical research fellow (grade AM2)	25.40	203.17
Total intervention cost			8041.45
Average cost per unit			618.57

Review of structured case records			
Component or step	**Resources**	**Cost per hour (£)**	**Total (£)**
Collation of existing records	Liaison with all Scottish gynaecology units 8 hours @ grade CN3 secretarial support	8.95	71.62
	Planning 8 hours @ clinical research fellow (grade AM2)	25.40	101.62
Preparation and revision	24 hours @ clinical research fellow (grade AM2)	25.40	609.52
	20 minutes each pre-testing on 3 consultants	48.75	48.75
	20 minutes each pre-testing on 3 staff nurses	13.75	13.75
Dissemination	4 hours @ grade CN3 secretarial support	8.95	35.81
Total intervention cost			881.04
Average cost per unit			67.77

Promotion of patient information booklet			
Component or step	**Resources**	**Cost per hour (£)**	**Total (£)**
Photocopying of illustrative copies	10 per unit @ 3p per page and 8 pages per copy		31.20
Promotion	Conducted during outreach meetings		
Total intervention cost			31.20
Average cost per unit			

Appendix 7J. Local coordinators, data collectors, and contacts for patient survey

Hospital	*Coordinator*	*Data Collectors*	*Patient survey contacts*
Aberdeen Royal Infirmary	Dr Gillian Flett	Ms Frances Findlay	Sr Louise Craigie Sr Jane Beattie
Ayrshire Central Hospital	Dr Nivison Russell	Sr Jackie McCallum	Sr Jackie McCallum
Borders General Hospital	Dr Roddy Campbell	Ms Marion McKenzie	SN Anne Simpson
Caithness General Hospital	Dr Adam Gordon	Ms Rona McLeod	Sr Karen Sandison
Dr Gray's Hospital	Dr David Evans	Ms Jane Gray	SN Avril Donaldson-Webster SN Gillian Main SM Lynne Ritchie
Dumfries & Galloway RI	Dr Michael Geals	Sr Joanne Bradley Sr Liz Young	Sr Liz Young
Falkirk & District Royal Infirmary	Dr Ken Grant	Ms Carol Davies	Sr Shona Lawlor
Forth Park Hospital	Dr Tahir Mahmood	Ms Morag Telfer	Sr Mary Lorimer Sr Louise Ewing
Glasgow Royal Infirmary	Dr Mary Rodger	Sr Anne Kerr	Sr Anne Kerr
Hairmyres Hospital	Dr Keith Spowart	SN Elizabeth Flanagan SN Eileen Smith	Sr Sandra Taylor
Inverclyde Royal Hospital	Dr Jim Robins	Sr Shirley Roche	Dr Jim Robins Sr Shirley Roche
Wishaw Hospital	Dr Chris Lennox	Sr Margaret Morgan	Sr Mary McCormick
Monklands Hospital	Dr T Dow	Sr Anne Lawrie	Sr Anne Lawrie
Ninewells Hospital	Dr Maggie Thomson	Sr Jackie Dunlop	Sr Jackie Dunlop Sr Sheila Black
Perth Royal Infirmary	Dr W D Phillips	Ms Fionna Clark Ms Rena McDonald	Sr Lorna Maule SM Iris Gray
Raigmore Hospital	Dr Lucy Caird	Ms Margaret Cameron Ms Jackie Campbell Ms Margaret Williamson	Sr Lynn Chalmers
Royal Alexandra Hospital	Dr Ken Muir	Ms Sandra Crawford	Sr Cathy Owens
Edinburgh Royal Infirmary	Prof Hilary Critchley	Ms Lorraine Adamson	Sr Margaret Barnet Sr Billie Paterson
Southern General Hospital	Dr Bill Naismith	SN Nikki Harvey	SN Nikki Harvey
St John's Hospital at Howden	Dr Tara Cooper	Ms Anne Close Ms Ona Lally Ms Eleanor Swan Ms May Wynne	Sr Margaret Cruikshanks
Stirling Royal Infirmary	Dr Wendy McMullen	Ms Alana Horsburgh	Sr Anne Lindsay
Stobhill Hospital	Dr Colin Forrest	Ms Margaret Burke Ms Anne Coyle	Sr Sheila McGuire
Vale of Leven Hospital	Dr Mike Haxton	SN Elsie McKechnie	Sr Janet Brown
Victoria Infirmary	Dr Douglas Mack	Sr Victoria Morrison	Sr Victoria Morrison SN Fiona King EN Anna Maclagan
Western Infirmary	Dr Judith Roberts	Ms Fiona McLeod	Sr Isabel Traynor Sr Theresa Docherty
Western Isles Hospital	Dr P Sarkar	Ms Anne-Marie MacDonald	Ms Anne-Marie MacDonald

Published papers

Foy R, Walker A, Penney GC. Barriers to clinical guidelines: the need for concerted action. British Journal of Clinical Governance 2001;6:166-174.

Foy R, Eccles M, Grimshaw J. Why does primary care need more implementation research? Family Practice 2001;18:353-5.

Foy R, MacLennan G, Grimshaw J, Penney G, Campbell M, Grol R. Attributes of clinical recommendations that influence change in practice following audit and feedback. J Clin Epidemiol 2002; 55: 717-22.

Foy R, Nelson F, Penney GC. Awareness of key recommendations from the Report on Confidential Enquiries into Maternal Deaths 1994-6 among obstetric and midwifery staff in Scotland. Journal of Clinical Excellence 2000;2:27-32.

Foy R, Penney G, Greer I. The impact of national clinical guidelines on obstetricians in Scotland. Health Bulletin 2001;59:364-372.

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10 March 2003

Professor Jeff Lucas
Dean of School of Health Studies
University of Bradford
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Dear Editor

Re: Reproduction of Paper

I am seeking permission to reproduce a copy of the paper below within the appendix of my PhD to be submitted to the University of Edinburgh.

Foy R, Walker A, Penney GC. Barriers to clinical guidelines: the need for concerted action. British Journal of Clinical Governance 2001;6: 166-174.

Thank you in anticipation.

Yours sincerely

Dr Robbie Foy
Clinical Senior Lecturer in Primary Care

Supported
Editor BJCG 17/3/03

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Original papers

Barriers to clinical guidelines: the need for concerted action

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Keywords

Clinical guidelines, Clinical governance, Obstetrics, Gynaecology

Abstract

Aims to provide a framework for identifying barriers to the implementation of a clinical guideline by examining a clinical effectiveness programme and a review of relevant literature. A total of 41 types of barrier were identified and categorised according to characteristics of the guideline to be introduced, the individuals who need to change behaviour and the organisation or environment in which the change is to occur. Several groups have the potential to overcome such barriers, ranging from individual clinicians to national policy makers. Multi-level as well as multi-faceted strategies may be required to overcome barriers to the effective implementation of clinical guidelines.

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Introduction

There is a widely acknowledged gap between the evidence base and the delivery of health care (Haines and Donald, 1998). The importance of reducing this gap and inappropriate variations in health care has been acknowledged in recent NHS policy initiatives in the UK, including clinical governance. Such initiatives are more likely to work, if, amongst other factors, they incorporate proven means of promoting best clinical practice (Bero *et al.*, 2000).

The Scottish Programme for Clinical Effectiveness in Reproductive Health (SPCERH) was established in 1997 and represents the first of a series of multi-professional programmes funded by the Clinical Resource and Audit Group (CRAG) of the Scottish Executive Department of Health. SPCERH attempts to bring together a wide range of educational, audit and research activities, which aim to promote evidence-based practice and policy in reproductive health care.

Clinical guidelines represent one of the principal means of disseminating best practice (Walker *et al.*, 2000) and form an integral component of the national quality-enhancing initiatives. However, it is recognised that passive methods, such as the simple distribution of guidelines, are relatively ineffective at improving clinical practice (NHS Centre for Reviews and Dissemination, 1999a). Practice may improve, but in a piecemeal fashion or at a slower rate than anticipated (Firth-Cozens, 1997). This has led to increased interest in more active implementation strategies. A growing body of evidence suggests that such strategies should be designed following the prior assessment of barriers to adoption (Davis *et al.*, 1995).

This article aims to provide a framework to help in the identification of barriers to the implementation of clinical guidelines.

Methods

We reviewed the scope and nature of barriers to the adoption of evidence-based care, encountered first, within SPCERH's own work and, second, by other initiatives concerned with the implementation of clinical guidelines or guidance. We identified further barriers via recent systematic reviews (Cabana

British Journal of Clinical Governance
Volume 6 · Number 3 · 2001 · 166–174

et al., 1999; Wensing *et al.*, 1999; Pagliari and Kahan, 1999) and other articles describing barriers to effective health care. However, it should be emphasised that our aim was not to undertake a further systematic review, but rather, by combining these sources, to provide an overview of reported barriers to the adoption of clinical guidelines.

Identified barriers were divided into three broad categories according to whether they related primarily to:

(1) characteristics of the guideline to be introduced;
(2) characteristics of the individuals who need to change; or
(3) characteristics of the organisation or environment in which the change is to occur.

We sought examples to illustrate each type of barrier either from existing literature or from SPCERH's own work. Although most examples relate to experiences within Scotland and to reproductive health care, their message is relevant to a wider audience. We also attempted to identify which professional group(s) might have the greatest potential to overcome each barrier. Professional groups considered included: national policy makers, guideline developers, local health service managers, trainers, clinicians and researchers.

Findings and implications for policy and practice

A total of 41 different types of barrier were identified. Ten relate primarily to characteristics of the guideline itself (Table I). These included its perceived validity and relevance as well as the practical aspects of implementation in a particular setting. Guideline developers or clinical effectiveness staff within NHS Trusts could address the majority of these barriers.

A total of 16 of the identified barriers relate primarily to characteristics of the individuals who need to change (Table II). These barriers fell into the broad categories of knowledge, beliefs and attitudes and skills or abilities. These are more likely to require interventions involving education, persuasion or training. However, some could be addressed by changes to the way in which services are delivered, or by introducing reminders. The potential to address these lies predominantly with trainers and clinicians themselves, either at local or national levels – through professional organisations, for example.

A total of 15 identified barriers relate mainly to characteristics of the organisation or environment (Table III). These included established procedures and processes, the culture of the organisation, resources and means of evaluation. Managers and policy makers have more power to address most of these barriers than do clinicians or guideline developers.

Patients can play an important role in improving practice. To date, the knowledge and expectations of patients have been identified in the research literature as a barrier to guideline implementation. However, this may not always be the case. Informed patients may facilitate rather than impede guideline implementation in some circumstances. Patient characteristics do not fit easily into the framework that we have described here and the 41st identified barrier has been termed "patient factors." However, the groups we have identified do have the potential to address both patient information needs and the abilities of clinicians to negotiate treatment decisions with their patients or to handle conflict. For example, guideline developers could consider producing materials for patients alongside those for clinicians; local tutors could introduce training in negotiation skills.

Some of the distinctions among barriers appear arbitrary. However, the framework that we describe here is not presented as a theoretical taxonomy, but as a checklist to guide those concerned with changing clinical practice. There may be further barriers that have not yet been identified through research studies or practical experience.

A number of interventions have been shown to be consistently effective at promoting behavioural change among health professionals, including the use of clinical prompts and reminders, interactive educational meetings and (in more limited circumstances) educational outreach visits (Bero *et al.*, 1998). Multifaceted (or combined) interventions tend to be more effective, because more than one barrier usually exists for each desired behavioural change (Cabana *et al.*, 1999). There is still a need for a greater theoretical understanding of how successful interventions work and for

British Journal of Clinical Governance
Volume 6 · Number 3 · 2001 · 166–174

Table I Barriers related to characteristics of the guideline to be introduced

Barrier	Example	Groups with potential to overcome
Validity		
1. Invalidity of guideline recommendations, i.e. when followed they fail to lead to the health gains and cost benefits predicted for them (Institute of Medicine, 1992; Eastwood and Sheldon, 1996)	Poorer quality studies assessing diagnostic tests may over-estimate their accuracy by up to three fold (Lijmer *et al.*, 1999)	Researchers Guideline developers
2. Insufficient quality control in guideline development process	Failure to make explicit link between recommendations and supporting evidence in 18 per cent of medical society guidelines published over 1988-1998 (Grilli *et al.*, 2000)	Guideline developers
Relevance		
3. Limited applicability of recommendations to clinical practice because of differences in population characteristics or availability of intervention (Mant, 1999)	Wider use of hysterosalpingography (HSG) as first line in the investigation of infertility – as recommended by clinical guidelines (Royal College of Obstetricians and Gynaecologists, 2000a) – limited by availability of appropriately trained radiologists	Researchers Guideline developers Managers
4. Uncertainty about the durability (or "shelf-life") of new research (Oswald and Bateman, 2000)	Variation in the use of agents to prevent or delay active pre-term labour because of evolving evidence about optimal choice of agent and regimen and selection of women most likely to benefit.	Researchers Guideline developers
5. Unavailability of direct evidence to answer clinically important questions	Lack of data indicating likelihood of myocardial infarction for young, low-risk women using combined oral contraception (Hannaford and Owen-Smith, 1998)	Researchers
6. Applying data from studies to individual patients with different levels of baseline risk (Mant, 1999)	Use of magnesium sulphate to prevent fits in pre-eclampsia despite lack of clear evidence of benefit (Gulmezoglu and Duley, 1998)	Guideline developers Clinicians
Practicality		
7. Imprecise or ambiguous wording of recommendations (Grol et al., 1998)	Ambiguity of recommendations to investigate "post-menopausal bleeding" because of varying criteria to diagnose menopause	Guideline developers
8. Disruption to routine practice (Grol et al., 1998)	Introduction of new interventions, e.g. medical, as opposed to surgical, abortion	Managers Clinicians
9. Low awareness of information sources or unavailability of evidence at point of need (McColl et al., 1998)	Limited or no access to Cochrane Reviews (Iqbal *et al.*, 1998; Paterson-Brown *et al.*, 1993)	Managers Clinicians Educators and trainers
10. Attainment of "ceiling effects," beyond which it is more difficult to change practice further	Lack of improvement in compliance with selected recommendations from Cochrane Reviews (Wyatt *et al.*, 1998)	Clinicians

British Journal of Clinical Governance
Volume 6 · Number 3 · 2001 · 166–174

Table II Barriers related to characteristics of the individuals who need to change

Barrier	Example	Groups with potential to overcome
Knowledge		
11. Lack of awareness that clinical practice may be inappropriate	Prescribing of ineffective drug therapy for endometriosis-related infertility (Penney and Templeton, 1995)	Educators and trainers Managers Clinicians
12. Over-estimation of self-reported performance, (Eccles et al., 1999) or perceived irrelevance of recommendations (Dunning et al., 1998)	Over-estimation of actual use of corticosteroids to prevent complications following pre-term labour (Iqbal *et al.*, 1998)	Educators and trainers Managers Clinicians
Attitudes and beliefs		
13. General hostility to guidelines (Cabana et al., 1999)	Fears that introduction of guidelines increases susceptibility to litigation or reduces scope for using clinical judgement (Dye *et al.*, 2000)	Guideline developers Education and training
14. Previous adverse experience of changing practice (Armstrong et al., 1996)	Experience of foetal death following use of external cephalic version in management of term breech (Burr *et al.*, 1999)	Educators and trainers Clinicians
15. Doubts over credibility of source or change agent (Oliver et al., 1996; Humphrey and Berrow, 2000; Kitson et al., 1998)	Rejection of patient information leaflet by midwives and ultrasonographers because of disagreement with its assessment of costs and benefits of routine ultrasound screening (Oliver *et al.*, 1996)	Guideline developers Educators and trainers
16. Hostility to challenges to established practices, including those where research has been outpaced by development (Grimes, 1993)	Routine use of *intra-partum* cardiotocography (CTG) despite doubts over the evidence base (Thacker and Stroup, 2000)	Educators and trainers Clinicians
17. Low outcome expectation, i.e. belief that following recommendation will not lead to expected outcome (Cabana et al., 1999)	Perceived low "returns" on preventive measures such as encouraging smoking cessation in pregnancy	Educators and trainers
18. Avoidance of recommendations because of perceived increased susceptibility to litigation	Over-investigation and management of women with mild hypertension in pregnancy because of concerns relating to the development of more severe hypertension (Scottish Obstetric Guideline and Audit Project, 1997)	Educators and trainers Managers
19. Not sharing information with patients because of perceived resistance or demands (McColl et al., 1998) or concern about raising anxiety levels	Ultrasonographers' "protection" of women from information about the potential harms of antenatal ultrasound, e.g. abnormal scan result leading to abortion of normal fetus (Oliver *et al.*, 1996)	Educators and trainers
Skills and abilities		
20. Lack of skills and time to undertake brief targeted searches for clinical evidence or guidelines	Undertaking apparently simple but time-consuming *Medline* searches	Educators and trainers
21. Lack of skills in critical appraisal (of clinical guidelines as well as original research) (McColl et al., 1998; Oswald and Bateman, 2000)	Over-estimation of benefits or risks from interventions when relative risk reduction is used (Bucher *et al.*, 1994), e.g. "risk of transfusion at time of abortion doubles for every two week increment in gestation"	

(continued)

Table II

Barrier	Example	Groups with potential to overcome
	(Royal College of Obstetricians and Gynaecologists, 2000b), fails to convey absolute risk of only 2/1,000 and the fact that abortion is a very safe procedure	Educators and trainers
22. Over-reliance on trusted or convenient sources of information (Slawson and Shaughnessy, 1997)	Seeking advice from colleagues or specialists without querying evidence base (Olatunbosun *et al.*, 1998)	Educators and trainers Clinicians
23. Lack of familiarity or self-efficacy, i.e. clinician belief that he cannot perform the task (Cabana et al., 1999)	Infrequent enquiry during antenatal consultations by midwives or obstetricians about domestic violence (Foy *et al.*, 2000)	Educators and trainers
24. Managing the complexity of adopting desired practice (Grol et al., 1998; Kitson et al., 1998)	Organisation of multi-disciplinary care and follow-up for women with gynaecological cancer (NHS Centre for Reviews and Dissemination, 1999b)	Managers Educators and trainers
Behaviour		
25. Limited ability of professionals to process all relevant information in clinical practice, especially during high pressure situations (McDonald, 1976)	Assessment of foetal distress during labour	Managers Educators and trainers
26. Lack of protected time and resources to plan changes in practice (Dunning et al., 1998; Grol and Wensing, 1995; Cabana et al., 1999)	Continuing use of intensive schedules of antenatal care despite evidence that reduced-visit schedules do not compromise safety (Hall *et al.*, 1980)	Policy makers Managers Educators and trainers

Table III Barriers related to characteristics of the organisation or environment

Barrier	Example	Groups with potential to overcome
Established practices and decision-making processes		
27. Over-reliance on passive methods of dissemination (Freemantle et al., 1999; Davis et al., 1995)	Passive dissemination of *Report of Confidential Enquiries into Maternal Deaths* and resulting lack of awareness of key recommendations among obstetricians and midwives (Foy *et al.*, 2000)	Policy makers Managers Educators and trainers
28. Poor targeting of guidelines	Inability of professionals and organisations to cope with proliferating quantities of clinical guidelines (Hibble *et al.*, 1998; Firth-Cozens, 1997)	Guideline developers Policy makers
29. Guideline "adopted" without consensus or adaptation to local circumstances (Grimshaw and Russell, 1993)	Imposition of national guidance without consultation – such as the requirements for "approval of independent sector places for the termination of pregnancy" by the Secretary of State for Health (Royal College of Obstetricians and Gynaecologists, 2000b)	Managers Educators and trainers
30. Failure to prioritise implementation (Dawson, 1997)	Coping with multiple external and internal priorities; the need to ensure that sufficient resources are provided for implementation relative to the production of evidence (e.g. from the Cochrane Library) (Iqbal *et al.*, 1998)	Policy makers Managers

(continued)

Table III

Barrier	Example	Groups with potential to overcome
31. Inertia of larger organisations or networks	Continuing use of intensive schedules of antenatal care, with duplications of care by obstetricians, GPs and midwives, despite evidence that reduced-visit schedules do not compromise safety and that many women can be cared for by GPs and midwives alone (Hall et al., 1980; Tucker *et al.*, 1996)	Managers
Culture		
32. Little or no history of multi-disciplinary working (Dunning et al., 1998)	Resistance to an expanded role for gynaecology nurses has slowed the introduction of medical abortion.	Managers Clinicians
33. Negative attitudes from colleagues or other professionals towards challenging existing practices or reinforcing new effective practices (McColl et al., 1998; Armstrong et al., 1996)	Resistance to adoption of routine antibiotic prophylaxis at Caesarean section despite Cochrane Review demonstrating efficacy (Smaill and Hofmeyr, 2000)	Clinicians Educators and trainers
Resources		
34. Opportunity costs of evaluating and changing performance	Establishment of guideline initiatives without link to audit	Managers
35. Diluted or non-implementation of proven interventions because of limited resources (Foy et al., 1999)	Rationing of *in vitro* fertilisation (Smith and Plomer, 1996)	Policy makers Managers
Knowledge and assessment of organisational performance		
36. Promotion of non-evidence based standards (Sheldon, 1998)	Failure of 82 per cent of published professionally-developed guidelines to explicitly link recommendations to strength of evidence (Grilli *et al.*, 2000)	Policy makers Managers Clinicians
37. Negative attitudes to clinical audit by clinicians and managers	Concerns over perceived threats to professionals, restriction of clinical freedom and increased workload (Johnston *et al.*, 2000), resulting in marginalisation of audit activities (Donaldson and Muir Gray, 1998)	Managers Clinicians Educators and trainers
38. Absence or poor quality of clinical audit (Kitson et al., 1998)	Insufficient resources to support audit and lack of expertise in conducting audit (Johnston *et al.*, 2000)	Managers Educators and trainers
39. Difficulty in measuring or interpreting outcomes (Dunning et al., 1999)	Unreliability of *in vitro* fertilisation league tables in assessment of units' performance because of year-on-year random variation and biases in presentation of results (Marshall and Spiegelhalter, 1998; Winston, 1998)	Policy-makers Managers
40. Short-term outlook rather than appreciation of long-term nature of achieving and sustaining change (Dunning et al., 1998)	Traditional short-term project funding of audit and guideline exercises (until recently) by CRAG National Projects Committee	Policy makers Managers
Patient factors		
41. Conflicting patient knowledge, expectations and preference over choices in clinical management (Oliver et al., 1996)	Demand for Caesarean section in the absence of medical indications (Paterson-Brown and Fisk, 1997)	Educators and trainers

British Journal of Clinical Governance
Volume 6 · Number 3 · 2001 · 166–174

more evidence on the cost-effectiveness of tailoring interventions specifically to identified barriers. Furthermore, although we have identified "barriers", it is important to note that such factors may facilitate improved practice if they operate the other way around (Kitson *et al.*, 1998). For example, previous positive experiences of change or availability of special skills become strengths to be considered in the design of any local implementation strategy.

Those with the greatest potential to address barriers range from individual clinicians to national policy makers – but it is seldom possible to identify a single group capable of effectively tackling a barrier in isolation. For example, developing clinical skills in order to follow guideline recommendations requires support from both local tutors and management to provide protected time and resources for training. Ultimately, the priority given to such training is determined by national policy-makers, for example, in establishing frameworks such as clinical governance to ensure that these needs are identified and met. Therefore, strategies to tackle barriers to change need to be multi-level as well as multi-faceted. A critical test of clinical governance and managed clinical networks will be the extent to which they can help prioritise and unite action across organisational and professional boundaries.

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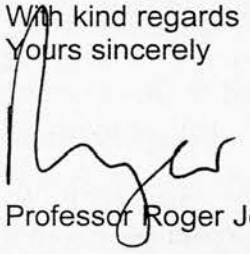

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Dear Dr Foy

RE: Family Practice, Vol. 18, 2001, pp. 353-5
Foy et al, 'Why does primary care need...'

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Family Practice

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Why does primary care need more implementation research?

Robbie Foy[a], Martin Eccles[b] and Jeremy Grimshaw[c]

Foy R, Eccles M and Grimshaw J. Why does primary care need more implementation research? *Family Practice* 2001; **18:** 353–355.

How can we improve the quality of primary care?

Clinical research continually produces new findings that can contribute to effective and efficient patient care. However, such research cannot change patient outcomes unless health services and health care professionals adopt them in practice. Uneven uptake of research findings—and thus inappropriate care—occurs across different health care settings, countries and specialities, as demonstrated by two papers on implementing evidence-based medicine published in this issue of *Family Practice*.[1,2]

In primary care, the detection and management of risks related to hypertension[3] or hyperlipidaemia are highly variable.[4] The impact of secondary prevention, including the administration of secondary prophylactic drugs to patients surviving a myocardial infarction, is reduced by similar disparities.[5–7] Much of this variation is not attributable to either patient or resource factors.

There are mounting expectations to deliver high quality primary care from governments impatient for results. Legitimate challenges to improve the quality of care[8] must be informed by research that can offer clinicians and managers effective and efficient means to enhance service delivery.[9] Implementation research (the scientific study of methods to promote the uptake of research findings, and hence to reduce inappropriate care) aims to inform policy decisions about how best to use resources to improve the uptake of research findings by testing approaches to change professional and organizational behaviour.

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What is known?

As with clinical care, systematic reviews of rigorous studies have contributed greatly to our knowledge about what works in changing professional and organizational behaviour. A recent overview of systematic reviews[10] suggested that it was possible to identify strategies that were more, or less, effective. Strategies such as postal distribution of guidelines or didactic educational sessions were suggested to be largely ineffective. Local consensus conferences, the use of opinion leaders or audit and feedback were of variable effectiveness, and strategies such as interactive educational workshops, reminder systems, educational outreach and multifaceted interventions were suggested as largely effective. This sounds very promising but, as is ever the case, the devil is in the detail.

Limitations of the evidence

On closer scrutiny, the evidence for effective interventions may not stand up to the real world of local implementation because of limited or unpredictable transferability. Our understanding of what makes professionals and organizations change (or not) is based upon superficial and, sometimes, hopeful interpretation of the processes. 'Academic detailing' (or educational outreach) involves the use of a trained person providing information, including feedback on performance, to professionals in their practice settings with the intent of changing behaviour. This appears to be effective when combined with 'social marketing' approaches that help identify and overcome barriers to change—but demonstrated benefits have been largely confined to prescribing in North America.[11] We need to understand in greater detail which factors influence the effectiveness of interventions in other circumstances, such as different settings, types of professional or targeted behaviours.

Attempts to generalize research findings to primary care (or any other setting) encounter three main problems. First, we are unsure of what factors are important in the relative success or failure of reported strategies

because of the lack of an established theoretical framework. Secondly, studies do not measure or report potential effect modifiers, e.g. the influence of different attributes of targeted behaviours on outcomes.[12] Thirdly, interventions are often poorly described—thus posing a problem for aggregation within systematic reviews and for subsequent interpretation in order to reproduce successful interventions. These problems are analogous to those of applying clinical research findings from secondary to primary care settings without considering population characteristics or available resources and skills.[13]

Systematic reviews of more rigorous evaluations (including randomized trials) indicate variable effectiveness within the same interventions, such as audit and feedback or use of local opinion leaders (people identified by their peers as being educationally influential. These variations might be attributable to the modifying effects of context and content. For example, it might be more feasible to identify and use local opinion leaders in secondary care settings than in primary care. Inconsistent findings might also be explained by variations in the intensity or quality of the interventions tested. Although prompts and reminders appear to be consistently effective, their frequency and proximity to the point of clinical decision making may influence the size of their impact.

Evidence on the effectiveness of certain strategies is sparse. For total quality management (TQM), uncontrolled evaluations have suggested benefit not borne out by randomized controlled trials.[14] Existing evidence may not be trustworthy or may be difficult to interpret because of methodological weaknesses, such as randomizing and analysing organization-wide interventions on an individual rather than group basis.[15]

Where effectiveness is consistently demonstrated, it is difficult to judge whether benefits are outweighed by costs. Few studies have assessed the direct costs of changing clinical behaviour, not to mention the indirect effects on health services following implementation strategies.[16] Resources are limited and any implementation strategies that exhaust these limited resources will not be sustainable in the long term. Those responsible for local implementation need to know as much about the cost-effectiveness of behavioural interventions as they do about that of clinical interventions.

What is needed?

Implementation research has to tackle a number of issues in order to improve the transferability of its findings. Studies require a conceptual framework within which to describe common elements of settings, individuals, targeted behaviours and interventions. Hence, it should be possible to identify what features influence the likely effectiveness of interventions.

Behavioural models that attempt to explain change require further development and testing in health care settings. We need to assess, for instance, how far changes in beliefs about research findings translate into changed practice.[17] Beyond explaining change, greater use should be made of theoretical models in the design of interventions.[18] Ultimately, the aim is to develop an empirical basis for selecting interventions given specific barriers and circumstances.

Better designed trials, more usually based upon cluster rather than individual randomization, will produce more valid (trustworthy) results.[19] Randomized trials of head to head comparisons are required to establish the relative effectiveness of interventions in the same setting.[19] Further work is needed to optimize the evaluation of evolving systems, such as computer support for clinical decision making and managed care pathways. Such evaluations should incorporate some assessment of the economic consequences of change strategies.

This research agenda demands stronger collaborations not only between different research teams and disciplines, but also among researchers, policy makers and those clinicians and managers responsible for local implementation.

Conclusion

Scope exists to improve the effectiveness of strategies to change behaviour. However, the current evidence base is limited. If efforts to improve the quality of primary care are to achieve their potential, we will need a new generation of theoretically derived, tailored, efficiency-based trials that will move us towards "evidence based medicine being complemented by evidence based implementation".[20]

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Dear Dr. Foy,

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Journal of Clinical Epidemiology

Attributes of clinical recommendations that influence change in practice following audit and feedback

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Abstract

The object of this study was to determine which attributes of clinical practice recommendations influence changes in clinical practice following audit and feedback. This was an observational study using multilevel modeling to examine the relationship between attributes of clinical practice recommendations and compliance with the recommendations before and after audit and feedback. Sixteen hospital gynecology units in Scotland participated in a national audit project. Clinical practice recommendations covering selected gynecological topics were developed and data collected to assess baseline (preintervention) compliance. Summaries of performance were fed back to consultant gynecologists in each hospital and follow-up (postintervention) data were collected. Trained audit assistants used standardized forms to abstract data from case notes. Compliance data were available at baseline and follow-up for a total of 42 clinical practice recommendations. Altogether, 4,664 case notes contributed to baseline data and 4,382 to follow-up data. Thirteen attributes describing clinical practice recommendations were developed, based upon previous work, and pretested. A panel of seven consultant gynecologists rated the extent to which each of the 42 recommendations possessed each of the 13 attributes. The main outcome measures were the association of each attribute with compliance and with changes in clinical practice. Recommendations compatible with clinician values and not requiring changes to fixed routines were independently associated with greater *compliance* at baseline and follow-up. However, recommendations incompatible with clinician values were independently associated with greater *change* in practice following audit and feedback. Attributes of recommendations may influence the effectiveness of audit and feedback in secondary care. Recommendations seen as incompatible with clinician values are associated with lower compliance but greater behavioral change following audit and feedback.

Keywords: Audit and feedback; Clinical practice guidelines; Professional practice; Behavior

1. Introduction

The implementation of valid clinical guidelines can improve the quality of health care [1]. Passive dissemination of a guideline is unlikely to lead to changes in clinical practice [2]. Combining more active interventions, such as reminders or interactive education, with guideline dissemination and implementation is more likely to change professional and organizational practice.

Various factors, or effect modifiers, can influence the effectiveness of such interventions [3]. Until recently, most research has focused on characteristics of clinicians or health care organizations, such as local attitudes or preparedness to change. However, the characteristics of clinical practice recommendations themselves may also influence their rate of adoption [4].

Grilli and Lomas first assessed the association between such characteristics and compliance with clinical guideline recommendations [5]. They reviewed published studies reporting compliance rates with 143 different recommendations developed or endorsed by official organizations. Compliance was higher for recommendations displaying "trialability" (which could be tried out temporarily and discarded if found wanting) and lower for complex recommendations. The "observability" of recommendations (how readily their benefits could be seen to be achieved) had no impact.

Grol et al. [6] assessed the extent to which Dutch general practitioners' compliance with 47 guideline recommendations was influenced by 12 characteristics (or attributes) of the recommendations. The guidelines were disseminated via journals and continuing medical education programs. Compliance was lower if recommendations were vaguely worded, incompatible with clinician norms and values, and disruptive to routine practice.

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Table 1
Summary of study methods

Context. Following a multicenter audit of gynaecological practice across 16 hospitals in Scotland, case note data on compliance at baseline and follow-up were available for a total of 42 clinical practice recommendations
Step 1. Development and pretesting of 13 attributes describing clincal practice recommendations
Step 2. Panel of seven gynaecologists, using a modified RAND consensual process, rates the extent to which each of the 42 recommendations displays each of the 13 attributes
Step 3. Regression analysis to examine the influence of each attribute on compliance and change in practice with the 42 recommendations. Multilevel modeling incorporated to account for potential clustering effects of hospital data

This previous work focused on the effects of various attributes on *compliance* with recommendations (i.e., a one-off measure of performance). However, clinical guidelines are produced to promote *change* in behavior (i.e., hereafter referring to a decrease or increase in compliance), which may be influenced by attributes different from those associated with compliance. We investigated whether various attributes of clinical practice recommendations influenced both compliance and change in clinical behavior among specialists participating in a national audit program.

2. Methods

Table 1 summarizes the context and main steps of this study, now described in detail.

2.1. Context: the Gynecology Audit Project in Scotland (GAPS)

This study assessed change in clinical practice within the context of a national audit and feedback program. Audit and feedback is defined as: any summary of clinical performance of health care over a specified period of time, which may include recommendations for clinical action [7]. Criteria for good quality care covering selected gynecological topics were developed and disseminated across Scotland between 1992 and 1997 [8–11]. The criteria were developed using an approach similar to that advocated for formal clinical guideline recommendations and are hereafter referred to as "clinical practice recommendations" [12]. Their development was based on reviews of available evidence, panel discussions, and questionnaire surveys of gynecologists and structured peer review.

Baseline compliance with the clinical practice recommendations was audited using data collected from case note reviews. Trained audit assistants used standardized forms to abstract data from case notes in 16 hospitals across Scotland.

Following the baseline audit period for each topic, a feedback report summarizing the agreed clinical practice recommendations, the results of the audit exercise, and suggestions for change in practice was circulated to all consultant gynecologists in Scotland. Gynecologists working in units contributing to data collection also received an individualized covering letter providing information to allow their unit to be identified, and highlighting the strengths and weaknesses of the local results. The circulation of the reports was complemented by presentations of the audit results at postgraduate meetings in individual hospitals and at national meetings. Follow-up data were then collected to help assess whether clinical behavior had changed in line with the recommendations. The cycle of audit and feedback lasted approximately 18 months for each topic.

Table 2
Number (percentage) of the 42 clinical practice recommendations judged by consensus panel to possess each attribute

Attribute	Number (%) of recommendations possessing attribute
Addresses common issue: concerned with a common clinical issue or a decision important in daily care	41 (97.6)
Precisely described: provides a sufficiently detailed and precise guide to clinical practice	40 (95.2)
Compatible: compatible with clinicians' current norms and values in practice	32 (76.2)
Key feature: Essential to the whole set of recommendations and to the ultimate goals	29 (69.1)
Based upon sound evidence: based upon sound scientific evidence including, as appropriate, clinical trials or metaanalyses	28 (66.7)
Fits patient expectations: is likely to fit in with patient expectations	15 (35.7)
Observable: the benefits of using this practice or policy over existing practices or policies can be seen quickly	8 (19.0)
Requires organizational change: requires changes in the way care is organized or additional resources	6 (14.3)
Requires changed routines: requires changes to fixed routines or habits	6 (14.3)
High profile: has a high profile in educational programs or the media	5 (11.9)
Complex: is complex and requires many steps to do or organize	3 (7.1)
Trialable: can be tried out and discarded easily	3 (7.1)
Requires new knowledge or skills: requires the learning of new knowledge or skills	0 (0)

2.1.1. Available clinical practice data

Baseline (hereafter referred to as "preintervention") and follow up ("postintervention") data were available from case note audits for a total of 42 clinical practice recommendations relating to four topics: induced abortion, endometrial sampling, laparoscopic sterilization, and infertility. Altogether, 4,664 case notes contributed to preintervention data and 4,382 to postintervention data.

2.1.2. Step 1: selection of attributes

Thirteen attributes of recommendations (e.g., whether the recommendation was based on sound evidence, whether

Table 3
Illustrative examples of clinical practice recommendations, compliance and ranges of compliance among hospitals

Preintervention compliance and degree of behavior change	Recommendation	Mean preintervention compliance in hospitals (% and range)	Mean postintervention compliance in hospitals (% and range)	Examples of attributes and clinician panel rating
Low compliance—low change	Laparascopic sterlization: prior to sterilization, women should be given an information leaflet summarizing the various factors covered in the counseling	7 (0–68)	8 (0–57)	Based on sound evidence: high Fits patient expectations: high Observable: low
Low compliance—moderate change	Induced abortion: the follow-up appointment should be within 14 days of the abortion	5 (0–18)	32 (0–93)	Common problem: high Compatible: low High profile: low
Moderate compliance—moderate change	Management of infertility: drug treatments for endometriosis in women with this condition and infertility do not improve conception rates and should not be prescribed for this purpose	45 (0–100)	70 (38–100)	Based on sound evidence: high Fits patient expectations: low Observable: low
High compliance—no change	Induced abortion: the woman's rhesus status should be ascertained, and rhesus prophylaxis given following abortion, if indicated	97 (86–100)	97 (91–100)	Compatible: high Based on sound evidence: high Requires change routines: low

it was compatible with clinician norms) were developed, based upon previous work [5,6], and modified following pretesting on a convenience sample of four consultant gynecologists (see Table 2 for list and Table 3 for illustrative examples.)

2.1.3. Step 2: rating of recommendations

A purposive sample of seven consultant gynecologists was recruited to form a consensus panel. Attempts were made to balance clinician age and their hospital characteristics (teaching and nonteaching; urban and rural).

Using a modified RAND process [13], the panel rated the extent to which each of the 42 gynecology recommendations displayed each of the 13 attributes. Initially, each panellist rated the recommendations independently using an ordinal 1–9 scale. The median scores and levels of agreement from this first round of rating were fed back at a panel meeting. Structured discussion centred on the recommendation attributes over which there was maximal discordance (defined as at least three panellists scoring 1–3 and at least three scoring 7–9). Much discussion concerned clarifying definitions of attributes or recommendations and the degree to which certain recommendations displayed certain attributes. Immediately after this discussion, panellists again independently rated the extent to which each recommendation possessed each attribute. A median score of 7 or more was used as the cutoff point for categorizing recommendations as possessing an attribute.

2.1.4. Step 3: regression analysis

Regression analyses were undertaken to assess the strength of associations between adherence to the recommendations and the extent to which each recommendation displayed each of the 13 attributes (as measured by the median panel rating). Initially the influences on compliance and behavior change were assessed for each attribute individually (univariate analyses). Subsequently, a multivariate analysis was undertaken to assess which attributes had the most significant independent effect on compliance and behavior change.

Analyses were performed relating to (a) preintervention compliance, (b) postintervention compliance, and (c) change in compliance. The effect of each attribute on change in compliance is presented as an interaction term, as recommended by Cook and Campbell [14].

There was marked variation in compliance among hospitals. Multilevel regression modeling was, therefore, adopted for all analyses. Multilevel modeling is designed for the analysis of hierarchical data, and thus allowed us to model patient outcomes while adjusting for the different hospital effects, for example, hospitals might differ according to whether or not they were teaching hospitals [15]. A two-level hierarchical linear model was adopted for all the analyses (patients within hospitals in this case), and a Normal error structure assumed. The multilevel regression modeling was undertaken using the statistical package MLWin. The subclustering of patients within clinicians was not incorporated in the model, as it was assumed that clustering would be most likely at the level of the hospital, as local management protocols, if any, would be instituted at the organizational level rather than at the level of the individual clinician. In addition, the intervention feedback was aggregated at the hospital level rather than the level of the individual clinician.

The number of cases available for the assessment of compliance with each of the 42 recommendations varied widely (from 10 cases to 1,510 cases). To avoid the possibility of spurious correlation arising from analysis based upon rate ratios (in this case percentage compliance), the outcome variable in all regression analyses was the actual number of compliant cases, with subsequent adjustment for the total number of cases in the regression model [16].

3. Results

3.1. Panel rating of GAPS recommendations

The number of clinical recommendations displaying each attribute varied widely (Table 2). For example, 40 (95%) of the 42 recommendations were judged to precisely describe recommended clinical practice, and 41 (98%) as addressing a common clinical issue. None were judged as requiring new knowledge or skills, and only 3 (7%) each as trialable or as complex.

The five attributes (precisely described, addresses common issue, requires new knowledge or skills, complex and trialable) displayed by over 90%, or under 10%, of recommendations were not included in further analysis, because of their lack of variation. Thus, the modifying effects of eight attributes on compliance and change were studied.

3.2. Influence of attributes on compliance

Overall mean compliance with the 42 recommendations was 58% preintervention and 61% postintervention, although there were marked variations in compliance among hospitals (illustrated in Table 3). (A full list of recommendations and panel ratings is available from the authors.) When considered separately, all eight attributes were significantly associated with compliance both before and after feedback (Table 4). The regression coefficients were smaller for the postintervention compliance—primarily a reflection of the narrower range generally seen in compliance scores postintervention. As such, there was less potential for the attributes of the recommendation to influence compliance in the postintervention phase. The following six attributes had positive effects on compliance both pre- and postintervention: based upon sound evidence; key feature; compatibility; fits patient expectations; high profile; and observable. Negative effects were associated with two attributes: requires organizational change; and requires changed routines.

When the impact of all attributes were considered together on multivariate analysis, only two attributes were found to be significantly and independently associated with compliance at both pre- and postintervention (Table 5). Compatibility was positively associated with compliance, i.e., the more the recommendation was compatible with clinician values, the higher the compliance. Requires changed routines was negatively associated with compliance, i.e., the more the recommendation required changes to routines, the lower the compliance. Compatibility was significantly correlated with the other seven remaining attributes in the model, and might represent a general marker for a range of attributes that influence practice.

3.3. Influence of attributes on behavior change

Considered separately, four attributes were significantly associated with behavior change. However, the directions of these associations were reversed in comparison with those obtained for compliance. The attributes positively associated with compliance (compatibility and key feature) were negatively associated with behavior change, and those negatively associated with compliance (requires organizational change and requires changed routines) were positively associated with behavior change (Table 4).

When the impact of all attributes were considered together on multivariate analysis, only *compatibility* was found to be significantly and independently associated with change in compliance. The more compatible the recommendation with clinician norms and values, the smaller the behavior change pre- to postintervention (Table 5).

4. Discussion

4.1. Principal findings

Certain attributes of clinical practice recommendations were associated with variations in compliance *and* behavior

Table 4
Univariate analyses of the association between eight attributes and complicance with recommendations

Attribute	Regression coefficient (95% CIs)		
	Preintervention compliance	Postintervention compliance	Change pre- to postintervention[a]
Compatible	8.94 (7.42, 10.46)	5.79 (4.43, 7.14)	−3.34 (−5.37, −1.31)
Key feature	6.97 (5.27, 8.66)	4.96 (3.48, 6.44)	−2.32 (−4.56, −0.08)
Based upon sound evidence	3.91 (1.84, 5.98)	3.75 (2.00, 5.50)	−0.30 (−3.00, 2.40)
Fits patient expectations	3.00 (1.07, 4.93)	1.93 (0.03, 3.57)	0.72(−1.79, 3.23)
Observable	5.06 (3.59,6.53)	3.42 (2.15, 4.69)	−1.68 (−3.62, 0.26)
Requires organizational change	−5.63 (−6.99, −4.27)	−3.66 (−4.84, −2.47)	2.19 (0.39, 3.99)
Requires changed routines	−6.04 (−7.26, −4.82)	−4.00 (−5.07, −2.93)	2.18 (0.56, 3.80)
High profile	4.84 (2.14, 7.54)	4.29 (2.41, 6.17)	−0.63 (−2.12, 3.38)

[a] Coefficient of interaction term.

Table 5
Results of multivariate regression analysis of the association between the attributes and compliance with recommendations

Variable	Regression coeffcient (95% CI)	Significance of regression
Preintervention compliance		
Compatible	6.76 (4.73, 8.88)	<.001
Requires changed routines	−2.52 (−4.10, −0.95)	
Postintervention compliance		
Compatible	4.26 (2.44, 6.08)	<.001
Requires changed routines	−1.77 (−3.19, −0.35)	
Change in compliance pre- to post- intervention		
Compatible	−3.34 (−5.37, −1.31)[a]	<.001

[a] Coefficient of interaction term.

change before and after an audit and feedback program in secondary care. Consistent with previous work [6], recommendations *compatible with clinician norms and values* and not *requiring changed routines* were independently associated with higher compliance. However, clinical practice recommendations are intended to change behavior, and a different picture emerged when changes in compliance following audit and feedback were examined. Recommendations less *compatible with clinician norms and values* were associated with greater improvements in clinical practice, probably because of a greater potential for change due to low baseline compliance. Those recommendations more *compatible with clinician norms and values* thus may have been associated with potential ceiling effects, with limited scope for further improvements in practice.

4.2. Strengths and weaknesses of the study

To our knowledge, this is the first study to investigate whether attributes of recommendations independently influence *change* in clinical behavior as opposed to *compliance*. Much implementation research is still based upon a "black box" approach but it is important to explore the potential impact of a range of effect modifiers (such as attributes of clinical practice recommendations) to improve our understanding of why interventions may or may not succeed in changing professional behavior.

We used a more rigorous consensus process than previous research to define the attributes of clinical practice recommendations, based upon the perceptions of our targeted clinicians. Given the retrospective design of this study, it is possible that panel ratings were biased by the gynecologists' knowledge of how widely certain recommendations were actually adopted in practice. The use of multilevel modeling, incorporating individual hospital effects, was justified given the marked variation in practice observed among different hospitals. Analyses based on patient level data, which did not account for "clustering" effects, might have overemphasized the significance of any results [15].

Case notes may not contain all relevant information to assess whether recommendations are followed in clinical practice. Although several clinical practice recommendations were concerned with adequate recording of actions in the case notes, it is possible that the use of such data might underestimate actual adherence to some recommendations. However, assuming such a bias applies equally to the pre- and postintervention data, it is unlikely to underestimate changes in behavior.

4.3. Meaning of the study (possible mechanisms and implications for clinicians or policy makers)

A range of interventions exists to improve clinical practice. Systematic reviews of rigorous evaluations suggest that some of these interventions are largely ineffective (e.g., postal distribution of guidelines alone) while others work more consistently (e.g., use of clinical prompts and reminders) [17]. However, it is often difficult to predict which interventions are best suited to particular circumstances. Audit and feedback is variably effective [18]; this may be related to factors such as the method of feeding back performance data to clinicians or the actual content of the recommendations.

In this study, audit and feedback appeared to be effective in promoting the implementation of recommendations judged to be less *compatible with clinician norms and values*. For example, in the care of women undergoing induced abortion, preintervention compliance was low (5%) for one such recommendation, "The follow-up appointment should be within 14 days of the abortion." Following audit and feedback, compliance increased moderately by 27% (to 32%). Feedback permitting comparisons among hospitals during the audit programme may therefore have prompted action on recommendations previously regarded as too disruptive or incompatible to implement. In contrast, preintervention was compliance was high (97%) for a recommendation rated as *compatible with clinician norms and values*, "The woman's rhesus status should be ascertained, and rhesus prophylaxis given following abortion, if indicated." Subsequently, there was little scope for improvement in compliance with this recommendation following audit and feedback.

Different attributes may have influenced change in clinical behavior following an intervention other than audit and feedback (e.g., interactive educational programs). For example, recent experience regarding the dissemination of four clinical guidelines within the context of a national clinical effectiveness program suggests that adherence to one guideline (albeit clinician reported) did not improve because of the relatively complex nature of its recommendations [19].

Implementation strategies, based upon a "diagnostic analysis"—identification of potential needs and barriers—are more likely to be effective [20]. Attributes of individual recommendations appear to influence both compliance and behavior change, and need to be considered when planning implementation activities. It is likely that the effects of different implementation strategies may be modified by the at-

tributes of recommendations. At present, there is only limited information about how such attributes modify the effects of implementation strategies; however, as further evidence becomes available consideration of the attributes of practice recommendations may assist in the choice of implementation strategy.

4.4. Unanswered questions and future research

Further research is required to determine how attributes of recommendations modify the effectiveness of different interventions in different contexts. These studies should focus on behavior change rather than compliance, and use the most robust estimates of behavior change, preferably from randomized trials.

5. Contributors

R.F. participated in designing the study, running the consensus panel, and data analysis. G.M. analyzed the data. J.G. suggested the original idea for the study, and participated in its design and analysis. G.P. participated in design of the study, operation of the consensus panel, and the original audit data collection. M.C. participated in design and analysis. R.G. participated in design of the study. All contributors participated in the writing of the study. R.F. is guarantor for the study.

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Awareness among obstetric and midwifery staff in Scotland of key recommendations from the *Report on Confidential Enquiries into Maternal Deaths in the United Kingdom 1994–1996*

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Objective To evaluate the impact of disseminating the *Report on Confidential Enquiries into Maternal Deaths 1994–1996.*
Design Telephone survey.
Setting Twenty-three consultant-led maternity units in Scotland.
Participants Obstetricians and senior midwives.
Main outcome measures Awareness of key recommendations from the report and participation in implementation activities.
Results Two hundred and one of 208 staff (97%) agreed to participate. One hundred and thirty-one (65%) stated they had read at least some of the report. A median of three of 18 key recommendations were recalled, with recall of newer issues being poorer. Although reported access to key clinical guidelines was high, other dissemination and implementation activities were used inconsistently, if at all.
Conclusion Publication of future confidential enquiry reports should be accompanied by active dissemination strategies, possibly emphasising newer or more important recommendations.

Keywords: clinical audit, maternity care, survey

Introduction

The series of reports dealing with confidential enquiries into maternal deaths (CEMD) aims to draw generalisable lessons for maternity care by scrutinising events preceding maternal deaths in the United Kingdom. Participation in these enquiries and implementation of subsequent recommendations represent core functions within clinical governance.[1] The last report, for the years 1994–1996, subtitled *Why Mothers Die*, also highlighted wider public health issues.[2] Many of the maternal deaths are associated with episodes of sub-standard care, but instances of such care related to mortality may represent only the 'tip of the iceberg', with a large proportion of 'near miss' events likely. Although maternal mortality has continued to fall, similar errors in clinical care tend to recur. The implementation of the report's recommendations therefore continues to represent a major challenge for maternity services, especially in the light of the professional time and interest invested in the conduct

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of the enquiries and production of the reports. Copies of the report are sent to all consultant obstetricians and heads of midwifery in Scotland. Given the multidisciplinary nature of maternity care, it is important that key clinical recommendations are disseminated widely. The 1994–1996 report was supplemented by an executive summary, listing key recommendations, intended for wider distribution among all staff involved in maternity care.

Effective dissemination represents a critical first step in implementation. This study aimed to assess awareness among obstetricians and midwives in Scotland of the key recommendations from the 1994–1996 report, and to determine their participation in local dissemination activities.

Methods

The sample consisted of duty obstetric (senior house officers, specialist registrars and consultants) and midwifery (midwives in charge of labour wards and antenatal clinics) staff from all 23 consultant-led maternity units in Scotland. Most units were sampled twice with five staff members being approached on each occasion, but in the three smallest units, only three staff members were approached. In one larger unit, only four staff members were eligible on the second occasion. Thus, 208 staff were approached for interview.

An interview schedule for a telephone survey was developed and pre-tested to include:

- awareness of key recommendations from the report and the main causes of maternal mortality,
- reported clinical practice,
- access to clinical guidelines,
- participation in educational activities relevant to the report.

Enquiry was made into recall of key recommendations, with minimal prompting by the interviewers. For the purposes of this study, mention of at least one aspect of a recommendation was counted as a positive response.

Where possible, the precise topic of the survey was not revealed prior to the interviews. The confidential nature of this survey and the fact that it was to assess dissemination of the report rather than individual competence were explained to all potential participants. The interviews took place 6 months after the report was published.

Data were entered into an Access database (Microsoft Access, 1997, INSO Corporation) and analysed using SPSS for Windows (version 8, 1997, SPSS Inc.). Median recall scores were compared using the Mann–Whitney U test with two-sided P values.

Results

Two hundred and one of 208 staff agreed to be interviewed (a response rate of 97%). Three refused to be interviewed and four could not be contacted after at least six attempts. Responders were evenly distributed by grade and discipline according to the sampling frame.

One hundred and eighty-five (92%) were aware of the latest report (Table 1) and 131 (65%) reported having read at least some of the full report or executive summary. Fewer had participated in educational meetings or tests of emergency protocols ('fire drills'). Reported access to clinical guidelines was high except for the management of women who declined blood products and the management of ectopic pregnancy. (The latter were mentioned as being more frequently located in gynaecological units.)

Each responder recalled a median of three out of 18 key recommendations. At least a third of responders recalled issues relating to the management of eclampsia and pre-eclampsia, protocols for emergencies, consultants' attendance and delegation, and prophylaxis for thromboembolism (Table 2). However, recall of certain preventive issues such as seatbelt use, domestic violence, antibiotic prophylaxis in caesarean section and awareness of puerperal sepsis was much lower. Forty-seven respondents (33%) were unable to recall any recommendations.

Asked about direct causes of maternal mortality, most respondents ranked thromboembolism and pregnancy induced hypertension within the top three but omitted amniotic fluid embolism (Table 3). Respondents were also less aware that epilepsy and psychiatric illness represented major indirect causes of maternal death. In response to a separate question about epilepsy, 120 of 163 staff involved in antenatal care (74%) could recall neither of the specific recommendations pertaining to personal safety (not bathing unsupervised and that friends or relatives know what to do in the event of a fit).

Respondents who reported having read at least some of either report recalled a median of three recommendations compared with 0.5 for those who had not ($Z = 6.73$, $2P < 0.001$). Respondents who had attended any educational meeting recalled a median of four recommendations compared with two for those who had not ($Z = 4.59$, $2P < 0.001$).

Table 1. Number and per cent of interviewees reporting participation in or access to dissemination activities

Activity	Number (%)
Recognition, receipt and reading	
Awareness of the Report	185 (92)
Received or seen a copy of the Full Report	119 (59)
Received or seen a copy of the Executive Summary	79 (39)
Read at least some of the Full Report	104 (52)
Read at least some of the Executive Summary	67 (33)
Training activities	
Lecture specifically on the most recent Report (didactic style)	19 (9)
Group tutorial specifically on the most recent Report (interactive style)	40 (20)
Tests of emergency obstetric protocols ('fire drills') in preceding 6 months	49 (24)
Access to local guidelines or policies	
Management of pre-eclampsia and eclampsia	195 (97)
Management of obstetric haemorrhage	186 (93)
Use of thromboprophylaxis	179 (89)
Antibiotic cover for caesarean sections	169 (84)
Management of women who decline blood products	102 (51)
Investigation and management of ectopic pregnancy	106 (53)

A total of 201 staff were interviewed.

Discussion

Overall awareness of the report's content was low, especially of those recommendations included for the first time in the current report. Although most staff reported access to major clinical guidelines, other educational efforts to disseminate key CEMD recommendations were used inconsistently, if at all.

The high response rate and quasi-random method of selecting participants improved the likelihood that the sample was representative of obstetricians and senior midwives in Scotland. Attempts were also made to minimise biases which might over-estimate awareness of the report's content. It is likely that the pressure of participating in telephone interviews led to an under-estimate of respondents' actual knowledge. However, responses to a postal questionnaire might have over-estimated awareness of recommendations, because some respondents might have been prompted to read the report as they answered questions. Furthermore, information on the relative levels of recall and recognition of recommendations indicates which recommendations appeared less important to clinical staff or require reinforcement in future dissemination activities.

This study was not designed to assess the effect of dissemination activities. Confounding may explain much of the apparent association between higher recall of recommendations and reading of the reports or attendance at educational meetings. For example, staff who received or read the reports may already have been more interested in the issues raised and so recalled more recommendations.

Knowledge of newer issues (e.g. the contribution of amniotic fluid embolism) appeared low compared with those mentioned in previous reports (e.g. consultants' attendance). The report incorporated a revised method for diagnosing deaths from amniotic fluid embolism, where the clinical picture alone may fulfil diagnostic criteria without pathological evidence. It is possible that the perceived contribution of post-partum haemorrhage to maternal deaths was

Table 2. Number and per cent of respondents recalling key recommendations from the report

Recommendation	Number (%)
Recognition of main direct causes of death	53 (26)
Importance of prompt diagnosis or referral of suspected serious disease	49 (24)
Identification of women at risk of post-natal mental illness or self-harm during antenatal care	15 (7)
Enquiry about domestic violence	8 (4)
Education of women about the use of seatbelts	4 (2)
Education of women about symptoms associated with pre-eclampsia	11 (5)
Education of women about first aid of epileptic fits	12 (6)
Early attention to chest or leg symptoms to exclude presence of thromboembolism	62 (31)
Management of eclampsia or pre-eclampsia by a single senior clinician	88 (44)
Pregnancy testing considered in any woman with unexplained abdominal pain	11 (5)
Prompt management of suspected ectopic pregnancy	33 (16)
Assessment of risk factors in considering prophylaxis against thromboembolism in all women undergoing caesarean section	66 (33)
Use of prophylactic antibiotics in caesarean section	9 (4)
Awareness of puerperal sepsis	6 (3)
Participation in confidential enquiries	6 (3)
Consultant attendance or appropriate delegation in emergencies	77 (38)
Need for units to have protocols for massive haemorrhage or pulmonary embolism	88 (44)
Unit 'fire drills' for emergencies	7 (3)

A total of 201 staff were interviewed.

raised following the recent dissemination of a guideline on this topic in Scotland.[3]

The report's public health messages appear to have been poorly assimilated, particularly those pertaining to the correct use of seatbelts and domestic violence. Such recommendations may have been given lower priority or seen as more problematic to implement. Several midwifery respondents mentioned that they were currently exploring acceptable ways to identify victims of domestic violence.

A re-audit of the implementation of the 1991–1993 report found improvements in the organisation of maternity services and availability of guidelines.[4] However, the simple distribution of printed educational material is relatively ineffective for improving clinical practice.[5] It is of concern that awareness of key recommendations was so low, especially given the high profile of the confidential enquiry into maternal deaths. Newer recommendations, such as the enquiry about domestic violence, may require greater emphasis in future reports and additional support to implement at a local level.

Conclusions

Participation in these confidential enquiries represents a core task in clinical governance. However, the time and effort expended in producing the reports need to be matched by appropriate dissemination activities. Among obstetric and midwifery staff in Scotland, knowledge of key recommendations from the last report (1994–1996) was poor. Educational efforts to disseminate recommendations were used inconsistently, if at all, at a local level. Publication of future reports should be accompanied by active dissemination and implementation strategies.

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Table 3. Respondents' knowledge of main causes of direct and indirect maternal deaths

Cause of death	Number (%) ranked amongst top three causes
Direct causes (in order of actual frequency)	
Thromboembolism	160 (80)
Pregnancy induced hypertension	173 (86)
Amniotic fluid embolus	19 (9)
Early pregnancy problems (e.g. ectopic)	11 (5)
Sepsis (or infection)	26 (13)
Haemorrhage	150 (75)
Uterine rupture	3 (1)
Fatty liver of pregnancy	1 (0)
Anaesthesia	16 (8)
Indirect causes	
Cardiac disease	143 (71)
Epilepsy	48 (24)
Psychiatric illness (including suicide)	20 (10)

A total of 201 staf were interviewed.

Clinical Resource and Audit Group of the Scottish Executive Health Department. RF is funded by a Medical Research Council/Scottish Executive special training fellowship.

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The impact of national clinical guidelines on obstetricians in Scotland

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Abstract

Objective: **To audit reported clinical practice in relation to four national obstetric guidelines on The Preparation of the Foetus for Preterm Delivery, The Management of Mild, Non-proteinuric Hypertension in Pregnancy, The Management of Pregnancy in Women with Epilepsy and The Management of Postpartum Haemorrhage.**

Design: **Questionnaire surveys before and after dissemination of the guidelines.**

Subjects: **One hundred and sixty one consultants and senior specialist registrars in Scotland.**

Results: **The response rates to the baseline and follow-up surveys were 85% and 74% respectively. Over 90% of the obstetricians kept the guidelines for reference and 85% had been prompted to change or reconsider their practice. Reported compliance improved significantly for six out of twenty nine recommendations covering: the use of tocolysis in women at risk of pre-term labour; the use of prophylactic antibiotics or entry to a clinical trial for pre-term, pre-labour rupture of the membranes; the initiation of steroid therapy in women with insulin-dependent diabetes mellitus; and the prescribing of periconceptual folic acid and vitamin K to women with epilepsy. There were no significant improvements in relation to mild, non-proteinuric hypertension or post-partum haemorrhage.**

Conclusions: **There were significant improvements in the reported management of women at risk of preterm labour and those with epilepsy. However, reported practice in relation to mild, non-proteinuric hypertension and post-partum haemorrhage has improved little. This is possibly because the guidelines for these topics were relatively complicated to understand and apply, and established patterns of practice more resistant to change.**

Keywords: **clinical governance; clinical guidelines; survey; maternity care.**

Background

Clinical guidelines and clinical audit represent two fundamental components of the NHS clinical effectiveness[1] and clinical governance[2] initiatives. These represent national efforts to promote more uniform standards of high quality, evidence-based care. Within these recent, quality-promoting initiatives, attempts have been made to bring together guideline, audit and related activities. Previously, audit[3] and guidelines[4] had been promoted as separate activities and were often undertaken in isolation.[5]

In Scotland, a national body, the Scottish Intercollegiate Guidelines Network (SIGN) has developed a rigorous methodology for the selection of topics for, and development of, clinical practice guidelines. Between 1995 and 1997, four obstetric guidelines (*The Preparation of the Foetus for Preterm Delivery, The*

Management of Mild, Non-proteinuric Hypertension in Pregnancy, The Management of Pregnancy in Women with Epilepsy and The Management of Postpartum Haemorrhage) were developed by multidisciplinary groups in accordance with this methodology.[7] Individual recommendations within the guidelines were graded as follows:[7]

- Grade A: at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation;
- Grade B: availability of well-conducted clinical studies but no randomised clinical trials on the topic of the recommendation;
- Grade C: evidence from expert committee reports or opinions and/or clinical experience of respected authorities.

The guidelines were disseminated by means of a national meeting attended by medical and midwifery representatives from all Scottish maternity units and by postal circulation to relevant medical and midwifery staff. Publication and dissemination were undertaken under the auspices of the Scottish Programme for Clinical Effectiveness in Reproductive Health (SPCERH), a national programme endorsed by the Scottish Branches of both the Royal College of Obstetricians and Gynaecologists and the Royal College of Midwives. National strategies for promoting clinical effectiveness have evolved from stand-alone projects towards integrated, multidisciplinary programmes. SPCERH represents such an initiative, bringing together educational, audit and research activities which relate to reproductive healthcare. However, the value of such programmes in improving healthcare and health outcomes requires evaluation.

In the spirit of an integrated clinical effectiveness programme, the development and dissemination of these four guidelines was complemented by an audit exercise which aimed to assess obstetricians' baseline compliance with the guideline recommendations and to assess any changes in practice subsequent to dissemination. The findings of this audit of self-reported practice are reported here.

Methods

A questionnaire enquiring into aspects of practice related to the guidelines, including brief case vignettes, was developed. It was sent to 161 senior obstetricians in 1997, comprising all consultants and all identifiable senior registrar/ year four and five specialist registrars in Scotland. The findings of the baseline audit questionnaire were disseminated at the time of distribution of the guidelines. A shorter questionnaire was posted to the same obstetricians two years later, containing a subset of the original questions which mainly addressed those recommendations where there was some potential for change in clinical practice. All initial non-responders to both questionnaires received one reminder.

Responses were entered into an Access database[8] and analysed using SPSS.[9] Responses were categorised as 'appropriate' if they were consistent with recommendations in the guidelines and included in the analysis only when matched questions from both the baseline and follow-up questionnaires had been answered. The exact matched pairs test was performed using Arcus[10,11] and two sided P values were used. To allow simpler presentation of results, the overall proportion and direction of change in practice is presented in addition to baseline compliance. As this way of presenting results could mask substantial shifts in opinion from compliant to non-compliant responses, large shifts (20% or more of respondents) in this direction were highlighted. One way analysis of variance (ANOVA) was used in the comparison of multiple means.

Results

During the period between the two surveys, 19 of the original 161 obstetricians retired from obstetric practice or moved outwith Scotland. Of the 142 obstetricians available for survey at both time points, 121 (85%) returned the baseline questionnaire and 105 (74%) the follow-up questionnaire. Ninety-two of these 142 obstetricians (65%) completed both questionnaires and results are subsequently based upon this group.

Eighty-four (91%) obstetricians reported that they had kept the guidelines for future reference whilst the others were uncertain of their location or had thrown them away. Seventy-eight (85%) reported that they had

Table 1. Receipt, adoption and audit of the guidelines (n=92)

	Recall receipt (%)	Adopted locally (%)	Used in local audit (%)
The preparation of the foetus for pre-term delivery	79 (86)	46 (50)	18 (20)
The management of mild, non-proteinuric hypertension	85 (92)	40 (43)	6 (7)
The management of pregnancy in women with epilepsy	86 (93)	53 (58)	13 (14)
The management of postpartum haemorrhage	78 (85)	47 (51)	23 (25)

changed or reconsidered aspects of their practice in response to the guidelines. Of these, 30 (33%) found the guidelines sufficiently relevant to prompt changes in some aspects of practice, whilst 48 (52%) were prompted to reconsider their practice. The remainder found them of general interest (12, 13%) of no real interest and (1, 1%). Approximately half of all respondents reported adopting the guidelines locally but fewer reported using them in local audit. Of the four guidelines, that on mild, non-proteinuric hypertension was least often adopted or used for audit locally.

Regarding preparation for preterm delivery, there were significant reported increases in both appropriate use of tocolysis and in consideration of prophylactic antibiotic therapy or entry to the MRC Preterm Antibiotic Uncertainty Study (ORACLE) in preterm pre-labour rupture of the membranes (PPROM). Compared with seven respondents who (appropriately) changed response to the avoidance of steroid therapy in a 28 year old primigravida presenting at 35 weeks gestation with PPROM, 17 changed response to prescribing steroids.

Despite positive trends, there were no significant improvements in the management of mild, non-proteinuric hypertension from a mixed baseline compliance. There was no change in the proportion of obstetricians reporting performing at least four out of the five basic investigations recommended in monitoring mild, non-proteinuric hypertension (50, 59% at baseline and 45, 53% at follow-up; P = 0.46).

Improvements were more pronounced in the reported care of pregnant women with epilepsy, with significant increases in the use of a higher dose of folic acid and combined administration of vitamin K. However, compared with nine respondents who changed (appropriately) to including combined oral contraception in options offered to women on enzyme inducers, 20 now would not.

Knowledge of recommendations for major obstetric haemorrhage from the 1991-3 Report on the Confidential Enquiry into Maternal Deaths (CEMD) did not consistently improve, although baseline knowledge was already high for four out of the six recommendations.[12] Compared with ten respondents who changed (appropriately) to setting up central venous pressure (CVP) monitoring, 21 would no longer do so.

Differences in reported mean compliance at follow-up was assessed according to whether recommendations were graded A, B or C. No significant differences were found (F = 1.53; DF=2; NS).

Discussion

Feedback of results from a baseline audit and dissemination of guidelines under the auspices of a national programme were followed by improvements in knowledge and self-reported obstetric practice. Overall, reported adherence to the guidelines increased significantly for six out of 29 recommendations.

This project represented one of the first attempts to complement national clinical guideline development with a related audit exercise. However, these results should be interpreted with appropriate caution as compliance with the guideline recommendations may have been overestimated for two reasons. First, 35% of the sample did not respond and obstetricians unaware of, or not following, the guidelines may have been less likely to respond to the survey. Second, self-reported practice may over-estimate actual clinical performance.[13]

Table 2. Guideline recommendations on the management of women at risk of preterm delivery, grade of recommendation and reported adherence

	Baseline number (%)	Overall change from baseline (%)	p
Prescription of ante-natal steroids for women at risk of pre-term delivery (n=83) **Grade A**	83 (100)	0(0)	1
Lowest gestation at which steroids would be considered (above 24 inconsistent with guideline, n=84) **A**	69 (82)	4 (5)**	0.39
Highest gestation at which steroids would be considered (34 to 36 weeks consistent with guideline, n=84) **C**	67 (80)	5 (6)	0.42
Use of tocolysis (Acceptable: rarely to permit intra-uterine transfer to a tertiary centre or to allow a course of steroids to be administered and for a maximum period of 48 hours, n=83) **A**	67 (81)	12 (14)	0.004
Use of prophylactic antibiotics or entry to ORACLE trial in the management of women presenting with preterm, pre-labour rupture of the membranes (PPROM) (n=84) A	52 (62)	20 (24)	<0.0001
A 25 year old primigravida with insulin-dependent diabetes (IDDM) and a twin pregnancy at 28 weeks gestation at risk of delivery in the next 7 days.			
Initiation of steroid therapy (n=83) **C**	77 (93)	6 (7)	0.03
Usual dosage if initiating steroid therapy (n=78) **A**	72 (92)	3 (4)	0.45
Use of tocolytic therapy to allow steroid therapy to have an optimal effect, assuming that contractions are regular and painful, and that vaginal examination has indicated the cervix is 50% effaced and 3 cm dilated (n=84) **A**	55 (65)	10 (12)	0.07
Indomethacin as preferred drug for tocolysis in IDDM (n=67) **B**	27 (40)	4 (6)	0.06
A 28yr old primigravida with no relevant medical or obstetric history presenting at 35 weeks gestation with PPROM			
Avoidance of steroid therapy (n=83) **C**	62 (75)	-10 (-12)	0.06
Use of prophylactic antibiotic therapy or entry to ORACLE (n=84) **A**	44 (52)	23 (28)	<0-001

Table 3. Guideline recommendations on the management of mild, non-proteinuric hypertension in pregnancy, grade of recommendation and reported adherence

	Baseline number	Overall change from baseline %	p
Use of Korotkoff phase IV (muffling of sounds) in measuring diastolic BP (n=84) **Grade C**	58 (69)	6 (7)	0.21
A patient attending for routine antenatal care is found to have a "spot" diastolic BP of 95 mmHg but no proteinuria. (Re-checking of BP within a short period and, if diastolic remains elevated, make arrangements for a further check in the hospital or community at least 4 hours later before initiating further investigations, n=86) **C**	55 (64)	9 (10)	0.09
Avoidance of anti-hypertensive treatment (or referral to a colleague for advice) for a 20 year old primigravida at 34 weeks gestation developing gestational hypertension (diastolic BP consistently 95 mmHg) but no proteinuria (n=86) **A**	73 (86)	4 (4)	0.42
Consideration of anti-hypertensive treatment (or referral to colleague for advice) for a 20 year old primigravida at 31 weeks gestation developing gestational hypertension (diastolic BP consistently 95 mmHg) but no proteinuria. (n=85) **A**	21 (25)	3 (3)	0.63
Methyldopa as preferred first line agent for treatment, where appropriate, of gestational hypertension (n=85) **B**	13 (15)	5 (6)	0.23
Twice weekly (every 3-4 days) follow up for BP check and urine testing for a 20 year old primigravida with a diastolic BP of 95 mmHg but no proteinuria at 34 wks gestation (n=85) **C**	40 (47)	5 (6)	0.49
Selection of investigations for intermittent assessment of the above woman (no more than two deviations from a list of 14 appropriate and inappropriate investigations. Appropriate tests are full blood count, platelet count, 'dipstick' testing for proteinuria, urea and electrolytes, and serum urate, n=85)	16 (19)	1 (1)	1

Table 4. Guideline recommendations on the management of pregnancy in women with epilepsy, grade of recommendation and reported adherence

	Baseline number	Overall change from baseline (%)	p
Periconceptual folic acid supplements at 4-5 mg/day (as for women with a previous history of neural tube defects) for women with epilepsy (n=78) **Grade C**	52 (67)	18 (23)	< 0.0001
Use of vitamin K 1 mg at birth for babies and treatment of mother with 20 mg orally daily from 36 weeks gestation for the prevention of haemorrhagic disease of the newborn (n=74) B	13 (18)	42 (58)	< 0.0001
Encouragement and support of breast feeding as for any other mother (n=76) **B**	67 (88)	6 (8)	0.07
Inclusion of combined oral contraception (COC) among the contraceptive options offered to women on enzyme inducers whilst encouraging the use of non-hormonal methods (n=79). **B**	42 (53)	-11 (A4)	0.06
Use of regimens containing higher doses of oestrogen as a first line when COC is chosen by a woman on an enzyme inducing anticonvulsant. (Any of: 50 ug pill, combination of two lower dose pills or taking three or more packs of pills in succession without a pill-free interval, n=79) **B**	58 (73)	6 (8)	0.38

At a significance level of five per cent at least one 'significant' change in practice will occur by chance following the multiple statistical tests performed in this study. Nevertheless, the overall trend was consistent with improved knowledge and practice and the limited number of obstetricians available for the survey may have constrained our ability to detect further significant changes. Whilst improvements in practice cannot be directly attributed to the methods of audit and guideline dissemination, they are consistent in direction and magnitude with those observed in a previous national audit programme.[16]

Our experience highlights lessons for similar initiatives to improve clinical practice. Several factors may explain why some guideline recommendations were apparently adopted more successfully than others. Reported practice improved across most aspects of the management of anticipated preterm labour, notably in the appropriate use of steroid therapy, tocolysis and prophylactic antibiotics in PPROM. Significant improvements occurred despite high baseline compliance. This may reflect obstetricians' growing acceptance of a reliable evidence base[15] and, perhaps, synergistic effects of educational activities undertaken by the ORACLE study group around this time to promote the trial. Similarly, the trends towards reported improved practice in women with epilepsy were encouraging.

However, considerable uncertainty persists regarding the optimal management of women with mild, non-proteinuric hypertension. There were wide variations in the reported frequency of follow up, selected investigations and therapeutic choices. Some choices of investigation (such as the use of ultrasound) may have been influenced more by availability and women's preferences than by guideline recommendations. Furthermore, once established, such clinical practices are difficult to alter.

Table 5. Guideline recommendations on the management of postpartum haemorrhage, grade of recommendation and reported adherence

	Baseline number (%)	Overall change from baseline (%)	p
Correct recall of recommendations made in the 1988-1990 Report on Confidential Enquiries into Maternal Deaths providing guidelines for the management of massive obstetric haemorrhage (n=86)			
Alert all of the following: anaesthetist, haematologist, blood transfusion and porters (true) **Grade C**	86 (100)	-1 (-1)	1
A minimum of 2 units blood should be ordered (true) **C**	31 (36)	12 (14)	0.06
Dextrans are recommended for transfusion until blood arrives (false) **C**	78 (91)	4 (4)	0.39
At least two intravenous lines should be set up using cannulae of not less than 14 gauge (true) C	86 (100)	-3 (-3)	0.58
Blood warming equipment is unnecessary (false) **C**	75 (87)	-6 (-7)	0.29
Central venous pressure monitoring should immediately be set up to ensure that therapy is safely controlled (true) **C**	57 (66)	-11 (-13)	0.07

The latest CEMD Report demonstrates that pregnancy induced hypertension is the second most common cause of maternal mortality.[16] Clinicians appear to be managing women with mild hypertension in pregnancy too aggressively and this probably reflects anxiety in missing or under-managing more serious disease. The guideline set out to support obstetricians in minimising clinical risk by offering a more structured, as well as efficient, approach to management. It is notable that 40 respondents (47% of 85) did not report the use of at least four out of the five basic investigations recommended in monitoring mild, non-proteinuric hypertension. This guideline possibly represents the most complex of the four to follow.

Approximately half of respondents did not correctly recall the CEMD Report recommendations that a minimum of two units of blood should be ordered and that central venous pressure monitoring should be employed in the management of massive obstetric haemorrhage. However, responses to the baseline survey indicated that all Scottish maternity units now have appropriate protocols in place. Rapid access to such protocols during clinical emergencies may be more important in improving standards of care than relying upon the limitations of memory.[17]

Compliance at follow up was unrelated to the grade of recommendations. Other characteristics of guideline recommendations may influence compliance, such as their compatibility with clinician norms and values, or disruption to routine practice.[18] The recommendations to use combined vitamin K regimens and the higher dose of folic acid supplement in pregnant women with epilepsy were graded B and C respectively. The precise nature of these recommendations may have contributed to the observed significant changes in reported practice. The instances where sizeable proportions of clinicians

shifted from compliant to non-compliant responses may be attributable to more ambiguous or complex recommendations (inclusion of COC as option for women receiving enzyme inducers) or inconsistency with overall management trends (avoidance of steroid therapy at 35 weeks gestation in PPROM). However, the trend away from CVP monitoring in massive haemorrhage seems more difficult to explain in this context.

It is acknowledged that the distribution of guidelines by itself is unlikely to change practice.[19] However, the dissemination and audit of clinical guidelines under a recognised national clinical effectiveness programme may contribute to consistent improvements in reported clinical practice. It is also important to learn why certain recommendations appear less acceptable to obstetricians. Those responsible for future guideline development and dissemination need to be able to anticipate barriers to implementation and design means of overcoming them. Whilst self-reported practice is not the most rigorous outcome measure, this survey has highlighted aspects of the guideline project requiring further evaluation. We are currently evaluating the impact of one of these guidelines by assessing both the effect upon actual clinical practice and the costs and benefits of the dissemination programme.

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